Robotic Assisted Surgery

Health Technology Assessment Program

UPDATED FINAL EVIDENCE REPORT

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Nature and Purpose of Technology Assessments

This technology assessment report is based on research conducted by a contracted technology assessment center, with updates as contracted by the Washington State Health Care Authority. This report is an independent assessment of the technology question(s) described based on accepted methodological principles. The findings and conclusions contained herein are those of the investigators and authors who are responsible for the content. These findings and conclusions may not necessarily represent the views of the HCA/Agency and thus, no statement in this report shall be construed as an official position or policy of the HCA/Agency.

The information in this assessment is intended to assist health care decision makers, clinicians, patients and policy makers in making sound evidence-based decisions that may improve the quality and cost-effectiveness of health care services. Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability.

This document was prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to support organizations and their constituent decision-making bodies to make informed decisions about the provision of health care services. The document is intended as a reference and is provided with the understanding that the Center is not engaged in rendering any clinical, legal, business or other professional advice.

The statements in this document do not represent official policy positions of the Center. Researchers and authors involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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Executive Summary

Background

Over the past 20 years, robotic surgical systems have been developed to assist surgeons with performing minimally-invasive procedures. Designed to increase surgical precision and minimize complications, these systems may afford better outcomes for patients than traditional laparoscopic surgery or open surgery. In 2000, the *da Vinci* robot was approved by the Food and Drug Administration (FDA) for general laparoscopic surgery. Numerous other indications for the *da Vinci* system have since been approved by the FDA, including urological procedures, gynecologic laparoscopic procedures, general thoracoscopic procedures, and others.

Clinical and epidemiological overview

Radical prostatectomy, hysterectomy, nephrectomy, and cardiac valve repair are among the most common applications of the *da Vinci* surgical system. While various cancer surgeries are often the primary indications for these procedures, other indications are also common, including benign neoplasms (e.g., uterine fibroids), as well as damaged or defective anatomical features (e.g., valvular heart disease). Many procedures are associated with increased complexity, operative times, and technical difficulty when attempted laparoscopically, and open laparotomy approaches are the current standard of care. For these procedures, robotic-assisted surgery is appropriately compared to the open approach.

Technology overview

Overall, the *da Vinci* system is designed to improve upon traditional laparoscopic surgery by providing three-dimensional visualization, improved ergonomics, and increased precision. Intuitive Surgical defines the *da Vinci* surgical system by its four main components: the surgeon console, the patient-side cart, the EndoWrist instruments, and the vision system. Surgeons use the computer console during procedures to view the surgical field and control the robotic arms. Three to four robotic arms, which are coupled to the patient-side cart, maneuver under the surgeon's direction. At the console, the surgeon uses EndoWrist surgical instruments that are designed to mimic human wrists by allowing seven degrees of motion. The vision system displays the surgeon's field of view to the operating room team.

Cost information

Both the necessity of intensive surgeon and surgical team training and the financial costs associated with these systems are significant considerations. The *da Vinci* system itself costs $1.0M to $2.3M, depending on options, and disposable instrument costs, per procedure, range from $1,300 to $2,200 in the United States. An annual service agreement totaling $100K to $170K per year is also required. Surgeons require initial device training from the manufacturer, as well as clinical training and continuing education. Depending on the complexity of the procedure and the surgeon's skill level, the learning curve may be steep and length of the clinical training period may be significant.

Policy context

The promises of minimally invasive surgery have captured the attention of patients, practitioners, and healthcare administrators alike. Faster recovery times and fewer complications would likely translate to shorter hospital stays, which may also help to minimize cost. Whether robotic-assisted surgery provides better outcomes than other minimally invasive techniques are important questions still under research. In 2007, the American Medical Association determined that an additional CPT code for robotic-assisted procedures was not necessary. As such, robotic-assisted procedures are reimbursable at the same rate as non-robotic procedures. Nevertheless, demand for robotic-assisted surgery is rising. Intuitive Surgical reported that 278,000 *da Vinci* procedures were performed in 2010, representing a 35% increase from 2009. An additional 30% increase in the number of procedures was expected for 2011. Prostatectomy procedures made up approximately one quarter of all robotic procedures performed in 2010, while hysterectomy procedures made up more than one third. As of the first quarter of 2012, 37 *da Vinci* Surgical Systems had been installed in the State of Washington. According to the company, since its first *da Vinci* System shipment, Intuitive Surgical has expanded its installed base to more than 1,500 academic and community hospital sites across the United States, while sustaining growth in excess of 25% annually.

Methods

Key Questions

KQ 1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes? Include consideration of short and long-term outcomes, and assessment of clinically meaningful outcomes.

KQ 2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches? Include consideration of morbidity, mortality, reoperation, excess bleeding, and extended hospital stay.

KQ 3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations? Including consideration of:

a. Gender;
b. Age;
c. Psychological or psychosocial co-morbidities;
d. Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes and high BMI;
e. Provider type, experience, or other characteristics and setting (including facility/team experience); and
f. Payer / beneficiary type including worker's compensation, Medicaid, state employees.

KQ 4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Methods – Evidence

For this WA HTA report, a search was conducted to identify published systematic reviews and individual studies (from January 2002 to January 2012) in the MEDLINE® database. An additional search using the Medicaid Evidence-based Decisions (MED) Project primary sources was completed to identify systematic reviews (SRs) and technology assessments (TAs) (from January 2002 to January 2012).

Articles were included if they compared a robotic-assisted procedure to the same type of procedure performed without robotic assistance, either by conventional laparoscopy or open laparotomy. For Key Questions #1, #2, and #3, systematic reviews (SRs), technology assessments (TAs), meta-analyses (MAs), randomized controlled trials (RCTs), controlled clinical trials or comparative observational studies were included. For Key Question #4, all relevant economic evaluations were included. Exclusions include obsolete robotic systems, studies that addressed pediatric populations, and those robotic systems not designed to improve procedures otherwise performed by laparoscopy or laparotomy.

The methodological quality of the included studies was assessed using standard instruments developed and adapted by the Center for Evidence-based Policy (CEbP) and the MED Project that are modifications of the systems used by National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN) (NICE 2009; SIGN 2009). Each study was assigned a rating of good, fair, poor, based on its adherence to recommended methods and potential for biases. The methodological quality of the economic studies was rated (good, fair, poor) using a standard instrument developed and adapted by the CEbP and the MED Project that are modifications of the British Medical Journal (Drummond 1996), the Consensus on Health Economic Criteria list (Evers 2005), and the NICE economic evaluation checklist (NICE 2009). The overall strength of evidence was rated (good, moderate, low, or very low) using a modified version of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (Guyatt 2008).

A systematic review using best evidence methodology was used to search and summarize evidence for Key Questions #1 through #3 as outlined below:

- Complete search of the Medicaid Evidence-based Decisions Project primary evidence sources;
- Existing good quality SRs and TAs summarized for each key question;
- If there were two or more comparable SRs or TAs identified and one was more recent, of better quality, or more comprehensive, then the other review(s) were excluded;
- Additional search of the MEDLINE® database completed to identify subsequently published studies. Individual studies published after the search dates of the last good quality review were appraised and synthesized with the results of the good quality SR; and

- If there were no good quality reviews identified, a search, an appraisal, and a summary of primary individual studies were completed for the last 10 years (January 2002 to January 2012).

For Key Question #4, all relevant economic evaluations were included.

Methods – Guidelines

A search for relevant clinical practice guidelines was conducted using a list of predetermined high quality sources from the MED Project and additional relevant specialty organizations and associations. Guidelines included were limited to those published after 2006. The methodological quality of the guidelines was assessed using an instrument adapted from the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration (AGREE Next Steps Consortium 2009). Each guideline was assigned a rating of good, fair, poor, based on the adherence to recommended methods and the potential for biases.

Methods – Policies

At the direction of the WA HTA program, select payer policies were searched and summarized. Aetna, Blue Cross Blue Shield, Group Health, and Medicare National and Local Coverage Determinations were searched using the payers' websites.

Findings

For the key questions, the core sources search identified 107 SRs and TAs, of which five met inclusion criteria. The MEDLINE® search retrieved 537 citations, of which 54 articles were included. Most of these studies were retrospective observational cohort studies and were rated as lower quality. An additional 223 studies were submitted during the public comment period for this report. Of these, 20 were found eligible for inclusion (19 cohort studies and one economic analysis). A detailed list of excluded studies and their reasons for exclusion is found in Appendix B. All included studies are detailed in the evidence tables included in Appendix D.

The findings below are grouped by procedure, with results for each key question #1 through #4 below the procedure.

Prostatectomy

There were 55 prostatectomy studies identified comparing robotic surgery with either open or laparoscopic surgery, which addressed the clinical key questions. There were 51 studies identified in the SR selected as the sole source of evidence for this procedure, the Ho [CADTH] (2011) TA. Study quality was assessed by Ho and colleagues as being high in one study, good in six studies, fair to good in 35 studies, poor to fair in eight studies, and poor in one study.[1] An

[1] CADTH describes their quality assessment tool as a modified version of Hailey et al.'s. Studies are rated on a scale of A to E, where A indicates high quality with a high degree of confidence in study findings; B indicates good quality with some uncertainty about the study findings; C indicates fair to good quality with some limitations that should be considered in any implementation of the study findings; D indicates poor to fair quality with substantial limitations in the study findings; which should be used cautiously; and E indicates poor quality with unacceptable uncertainty in the study findings.

additional four studies were identified updating this TA which were quality rated using a standard CEbP tool. One study was quality rated as good, one as fair, and two as poor.

- KQ1: There is moderate strength of evidence suggesting that the robotic-assisted radical prostatectomy (RARP) procedure, compared to open or laparoscopic approaches, was associated with shorter hospitals stays and reduced blood loss and transfusion rates. There is moderate strength of evidence that the robotic procedure had increased operative times, reduced positive-margin rates, increased urinary continence, and greater likelihood of sexual function compared to open surgery. There is moderate strength of evidence to suggest that RARP, compared with a laparoscopic approach, had reduced operative times and no difference in positive surgical margin rates. There is low strength of evidence that those undergoing robotic prostatectomy and the open procedure had similar biochemical recurrence-free survival.

- KQ2: There is moderate strength of evidence that RARP complication rates are not significantly different compared to open radical prostatectomy (ORP) or laparoscopic radical prostatectomy (LRP) procedures.

- KQ3: There is moderate strength of evidence that surgeons experienced in RARP were noted to have improvements in most clinical outcomes (except estimated blood loss [EBL]), when compared to less experienced surgeons.

- KQ4: The overall strength of the economic evaluation evidence for the following findings is moderate:

    - Comparisons between the various prostatectomy procedure groups (robotic, open, laparoscopic), did not reveal clinically important differences in the major outcomes (mortality, morbidity, quality of life [QoL], disease recurrence).

    - A cost-minimization study found that RARP was more expensive than ORP (incremental cost $3,860 per patient) and LRP (incremental cost $4,625). The incremental costs of RARP might have been reduced by increasing caseload, with significant cost reductions seen in the first 200 cases. A benefit of using the robot is a potential saving on hospitalization costs because of reduced lengths of hospital stay. The cost of the robot included in this economic analysis is for the newer model (*da Vinci* Si; US$2.6 million). However, the model reported in most of the literature is the older model (*da Vinci*; US$1.2 million). If this analysis had been carried out using the costs of the earlier model, the increased incremental costs of both comparisons (RARP vs. ORP and RARP vs. LRP), would have been roughly half what is reported above.

Hysterectomy

There were 34 hysterectomy studies identified comparing robotic surgery to either open or laparoscopic surgery, which addressed the clinical key questions. There were 26 studies identified in the SR selected as the sole source of evidence for this procedure, the Ho [CADTH]

(2011) TA. Study quality was assessed by Ho and colleagues as being good (five studies), fair to good (16 studies), and poor to fair (five studies). An additional eight studies were identified updating this TA, which were quality rated using a standard CEbP tool. Two of these studies were quality rated as good, two as fair, and four as poor.

- KQ1: There is moderate strength of evidence that robotic hysterectomy, compared to open hysterectomy, was associated with increased operative times, shorter length of stay (LOS), reduced risk of transfusion, and reduced EBL. The strength of evidence regarding robotic compared to laparoscopic hysterectomy is moderate for shorter LOS, and reduced EBL, and no statistically significant differences for operative duration or risk of transfusion. The strength of evidence is low that robotic hysterectomy and laparoscopic hysterectomy were associated with similar cancer recurrence rate at approximately 2.5 years. The strength of evidence is low that robotic hysterectomy was associated with lower pain scores initially, but similar pain score later when compared to laparoscopic hysterectomy.

- KQ2: The overall strength of evidence is moderate that robotic hysterectomy has lower incidence of complications than laparoscopic and open approaches. Further, the strength of evidence is moderate that the types of complications reported are similar between groups.

- KQ3: There is low strength of evidence, based on consistent findings across three studies, that robotic versus open hysterectomy in obese and morbidly obese patients results in increased operative time but reduced EBL, LOS and rates of complications. There is low strength of evidence that complications associated with open surgery may be more severe than those associated with robotic surgery among obese women. There is low strength of evidence that surgical proficiency is achieved earlier with robotic than laparoscopic total hysterectomy approaches. There is low strength of evidence that surgeon experience can influence robotic hysterectomy outcomes in terms of EBL and operative time, while outcomes after laparoscopic hysterectomy are not significantly different depending on surgeon experience.

- KQ4: The strength of the economic evaluation evidence is moderate that robotic surgery was generally the most costly, followed by open, and then by laparoscopic approaches. The strength of evidence is moderate that these costs were influenced primarily by operative times, LOS, and the cost of supplies, and that the incremental costs were influenced by robotic caseload. There is a very low strength of evidence that postoperative pain management costs were lower in robotic hysterectomy than traditional laparoscopic hysterectomy.

Nephrectomy

There were 12 nephrectomy studies identified comparing robotic surgery with either open or laparoscopic surgery, which addressed the clinical key questions. There were 10 studies identified in the SR selected as the sole source of evidence for this procedure Ho [CADTH]

(2011) TA. Study quality was assessed by Ho and colleagues as being good (one study), fair to good (eight studies), and poor to fair (one study). An additional two studies were identified updating this TA, which were quality rated using the standard CEbP tool. These two studies were quality rated as good. Most of these studies were observational and retrospective in design, and were rated as low quality on this basis.

- KQ1: There is low strength of evidence that robotic compared to laparoscopic partial nephrectomy was associated with shorter LOS, reduced warm ischemic time, mixed results in operative duration, and no significant differences in EBL or risk of transfusion. There is very low strength of evidence that robotic radical nephrectomy, compared to a laparoscopic approach resulted in longer operative times, but similar blood loss, incidence of transfusion and LOS. There is very low strength of evidence that robotic radical nephrectomy, compared to open radical nephrectomy, resulted in longer operative times, shorter LOS, lower EBL and similar transfusion rates.

- KQ2: There is very low strength of evidence that robotic partial nephrectomy and laparoscopic partial nephrectomy had similar complication rates. There is very low strength of evidence that robotic, laparoscopic and open radical nephrectomy had similar complication rates.

- KQ3: There is very low strength of evidence that robotic partial nephrectomy, compared to a laparoscopic partial approach resulted in no changes in selected surgical outcomes associated with a learning curve.

- KQ4: There is very low strength of evidence that the direct and indirect costs for robotic nephrectomy are higher than laparoscopic nephrectomy, but there were mixed results when compared to open surgery. The limited information regarding patients and interventions make drawing conclusions from this cost information unclear.

Cardiac Surgery

There were nine studies identified comparing robotic-assisted with non-robotic-assisted cardiac surgeries, which addressed the clinical key questions. Eight of these studies were identified in the SR, selected as the sole source of evidence for this procedure Ho [CADTH] (2011) TA. Study quality was assessed by Ho and colleagues as being high quality (one study), fair to good quality (six studies), and poor to fair quality (one study). An additional study was identified updating this TA, which was quality rated as good using a standard CEbP tool. Most of these studies were observational and retrospective in design, and were rated as lower quality on this basis.

- KQ1: The strength of evidence is low that the robotic procedures were associated with longer operative time and shorter LOS, but no statistically significant differences in transfusion rates when compared to non-robotic procedures. These studies were limited by small sample sizes and various technical detail differences across interventions. The generalizability of these results is unclear.

- KQ2: There is low strength of evidence on adverse events. Complication rates are mixed among intervention groups.

- KQ3: There is low strength of evidence that surgical experience improved robotic mitral valve repair perioperative outcomes compared to open surgery. Evidence which addresses this key question is limited to a single study of one type of the various cardiac surgeries included in this topic. These findings, therefore, cannot be generalized and the overall strength of evidence for all other cardiac surgery outcomes is very low.

- KQ4: The overall strength of evidence on robotic-assisted cardiac procedures is low that the robotic compared to open surgery groups incurred higher average patient costs. However this was consistent findings across all types of cardiac procedures analyzed. The evidence base for cardiac surgery is limited with small sample sizes and many different types of interventions reported.

Adjustable Gastric Band

There were two studies which compared robotic-assisted to laparoscopic gastric banding approaches, which were quality rated using the standard CEbP tool. One study was assessed as being of good quality and the other rated as poor quality.

- KQ1: There is low strength of evidence that there is no significant difference in LOS, weight loss at one year, and incidence of conversion to open procedure between robotic-assisted surgery and laparoscopic gastric banding. There is mixed evidence that operative time was longer in those undergoing robotic surgery, and so the strength of evidence on this outcome is very low. Studies were retrospective and observational only.

- KQ2: There were no clinically significant differences between the two interventions, based on a low overall strength of evidence for all safety and adverse event outcomes. Studies were retrospective and observational only.

- KQ3: In the sub-group of morbidly obese patients, there is low strength of evidence that robotic versus laparoscopic gastric banding resulted in shorter operative times in patients with BMIs of 50 kg/m^2 or greater. There were no significant differences between groups for LOS, weight loss at one year, and incidence of conversion to open procedure, based on low strength of evidence. Overall, no clinically significant differences were apparent between the two interventions.

- KQ4: The overall strength of evidence is very low that robotic-assisted surgery was more expensive than the laparoscopic procedure. However, evidence was limited as the costs included in the estimate were not described.

Adnexectomy

One SR included a single study comparing robotic-assisted and laparoscopic adnexectomy procedures. The authors of the SR did not report the quality assessment rating of this study.

- KQ1: There is low strength of evidence that robotic-assisted adnexectomy was associated with longer surgical duration compared to laparoscopic adnexectomy. All other measured outcomes were similar, based on low strength of evidence.
- KQ2: No evidence was identified that addressed this key question.
- KQ3: No evidence was identified that addressed this key question.
- KQ4: No evidence was identified that addressed this key question.

Adrenalectomy

There was one study which compared robotic-assisted to laparoscopic adrenalectomy procedures, which were quality rated using the standard CEbP tool. This study was assessed as being of poor quality.

- KQ1: The overall strength of evidence is very low that robotic-assisted adrebakectint compared to tolaparoscopic adrenalectomy had no significant differences for operative times, morbidity, pain, quality of sleep, and sleep duration.
- KQ2: No evidence was identified that addressed this key question.
- KQ3: No evidence was identified that addressed this key question.
- KQ4: No evidence was identified that addressed this key question.

Cholecystectomy

This SR included one RCT and three cohort studies comparing robotic and laparoscopic cholecystectomy. The authors of the SR did not report the quality assessment ratings of these studies. Two subsequent studies were identified that compared the same intervention groups, which were quality rated using the standard CEbP tool. Both were rated as being of poor quality.

- KQ1: The overall strength of evidence is low that robotic-assisted cholecystectomy was associated with longer operative times but reduced LOS when compared to the laparoscopic procedure. The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias.
- KQ2: The overall strength of evidence is low that robotic cholecystectomy and laparoscopic cholecystectomy had similar complication rates.

- KQ3: Findings are mixed as to the differential efficacy of robotic-assisted surgery depending on provider experience. As such, the overall strength of evidence on the impact of surgeon experience is very low.

- KQ4: Low strength of evidence suggests that robotic surgery was associated with increased costs when compared to laparoscopic surgery.

Colorectal Surgery (Colorectal Resection, Colectomy, Mesorectal Excision)

A SR included seven controlled, nonrandomized studies which compared robotic-assisted and laparoscopic approaches for colorectal resection. The authors of the SR rated all seven studies as good quality. Seven studies were subsequently identified which addressed this topic, which were quality rated using the standard CEbP tool. All of these studies were rated as being poor quality.

- KQ1: There is moderate strength of evidence that robotic surgery was associated with lower EBL, shorter LOS, similar time to bowel function recovery, and similar time to oral diet when compared to laparoscopic procedures. The preponderance of evidence suggests that robotic surgery was associated with longer operative times than open or laparoscopic procedures, but the mixed findings reported result in an overall low strength of evidence. There was significant heterogeneity across these studies in terms of baseline differences between groups, and the indications for intervention. Additionally, the observational design of most studies increases the risk of selection bias in favor of the robotic group.

- KQ2: The overall strength of evidence is low that robotic surgery compared to laparoscopic surgery did not significantly differ in complication rates.

- KQ3: There is low strength of evidence that surgeon experience influenced operative time outcomes between laparoscopic and robotic surgery.

- KQ4: The overall strength of evidence is low that higher costs, both direct and indirect, were associated with robotic compared to laparoscopic colon resection procedures. The cost data in these studies is presented without supporting detail and conclusions drawn from these figures are speculative.

Cystectomy

A SR included four studies which compared robotic-assisted and open (three studies) or laparoscopic (one study) approaches for radical cystectomy. The authors of the SR did not report the quality assessment ratings of these studies. Three subsequent studies were identified, all of which compared robotic-assisted to open cystectomy for treatment of bladder cancer and were quality rated using the standard CEbP tool. One study was rated as good quality and two as fair quality.

- KQ1: The overall strength of evidence is moderate that robotic surgery compared to open radical cystectomy was associated with decreased blood loss. There is moderate

strength of evidence that robotic surgery compared to open radical cystectomy results in increased operative times and decreased LOS. There is very low strength of evidence to show that robotic compared to laparoscopic radical cystectomy is associated with similar operative times, similar LOS, decreased blood loss, and lower transfusion rates. The study designs were observational and mostly retrospective in nature which can induce selection bias.

- KQ2: There is moderate strength of evidence that there were not significant differences in complication rates among types of cystectomy procedures.
- KQ3: No evidence was identified that addressed this key question.
- KQ4: This economic review presented a model which indicates that urinary diversion choices can influence costs by changing the incidence of associated complications, which are costly. This is contrary to the clinical effectiveness evidence which shows that robotic surgery compares well with other techniques in terms of complications. Therefore, the assumptions of this study are speculative as are their conclusions. The overall strength of evidence for economic outcomes related to robotic versus open cystectomy is low.

Esophagectomy

Eight studies (N=130) were identified in a SR of this procedure, all of which were non-comparative case series studies. The details of the perioperative outcomes for robotic-assisted esophagectomy are detailed in Appendix D. The authors of the SR did not report the quality assessment ratings of these studies.

- KQ1 to 4: There was insufficient evidence to address these key questions due to the lack of comparative studies.

Fallopian Tube Reanastomosis

A SR identified two studies that compared robotic to open fallopian tube reanastomosis. The authors of the SR did not report the quality assessment ratings of these studies.

- KQ1: Low strength of evidence indicates that robotic and open fallopian tube reanastomosis produced similar outcomes in terms of LOS, pregnancy rate, miscarriage rate, ectopic pregnancy rate, intrauterine pregnancy rate, and EBL (Reza 2010). Low strength of evidence suggests that surgical duration was longer with robotic surgery, but women were able to return to work approximately two weeks sooner, on average (Reza 2010). Observational study designs and small sample size limited these findings.
- KQ2: There is low strength of evidence that there were no significant differences in complications arising from robotic and open fallopian tube reanastomosis. Observational study designs and small sample size limited these findings.
- KQ3: No evidence was identified that addressed this key question.

- KQ4: There is low strength of evidence that robotic surgery was associated with higher costs than open surgery for tubal reanastomosis. These findings were largely limited by the failure to report how these costs were calculated, but also by the limitations of the underlying evidence presumably used to inform their calculations.

Fundoplication

A SR included four RCTs and five nonrandomized studies which compared robotic-assisted and laparoscopic approaches for fundoplication for the treatment gastroesophageal reflux. The authors of the SR did not report the quality assessment ratings of these studies.

- KQ1: There is moderate overall strength of evidence that LOS and operative time were similar between robotic and laparoscopic fundoplication.
- KQ2: There is moderate overall strength of evidence that complications were similar between robotic and laparoscopic fundoplication.
- KQ3: No evidence was identified that addressed this key question.
- KQ4: There is low strength of evidence suggesting that laparoscopic procedures had decreased costs compared with robotic fundoplication.

Gastrectomy

There were two SRs which addressed this procedure for the treatment of gastric cancer. One SR included two studies comparing robotic and laparoscopic gastrectomy; the authors did not report the quality assessment ratings of these studies. Another SR (one study) compared robotic and open approaches. This study was rated by the authors as D level (low quality) of evidence. In addition, there were two subsequent studies identified comparing robotic and laparoscopic gastrectomy, which were quality rated using the standard CEbP tool. Both studies were rated as poor quality.

- KQ1: The overall strength of evidence for all reported comparators and outcomes is low. Robotic gastrectomy may have some benefits over laparoscopic procedures (e.g., faster time to bowel function recovery) and open procedures (lower EBL). However, surgery time was consistently longer in robotic procedures compared to laparoscopic or open gastrectomy across all of the identified evidence. Statistically non-significant or mixed findings were reported for other outcomes, including EBL (robotic vs. laparoscopic), LOS, lymph node yield and dissection time, time to diet resume normal diet, white blood cell count, and C-reactive protein levels. These findings are limited by observational study design, potential selection bias from having younger individuals in the robotic treatment arms, and insufficient follow-up.
- KQ2: The strength of the evidence on complications arising from robotic, laparoscopic and open gastrectomy is low. However, the evidence suggests that the incidence of complications was similar between surgical modalities.
- KQ3: No evidence was identified that addressed key question.

- KQ4: There is low strength of evidence that robotic gastrectomy was associated with higher hospital costs than laparoscopic gastrectomy. These findings are substantially limited in their generalizability, as the methods used to calculate these figures were not described.

Heller Myotomy

One SR included three non-randomized studies which compared robotic and laparoscopic approaches for Heller myotomy to treat esophageal achalsia. The authors of the SR did not report the quality assessment ratings of these studies.

- KQ1: The strength of evidence is low for no significant difference in operative duration between intervention groups.
- KQ2: The strength of evidence is low for reduced incidence of esophageal perforations during robotic compared to laparoscopic procedures.
- KQ3: There is low overall strength of evidence that robotic and laparoscopic Heller myotomy procedures have no statistically significant differences in terms of surgeon learning curve.
- KQ4: No evidence was identified that addressed key question.

Ileovesicostomy

A single, good quality, retrospective study (n=15) was identified which compared robotic and open ileovesicostomy techniques for the treatment of adult, neurogenic bladder patients. This study was rated using a standard CEbP tool.

- KQ1: There is limited evidence from a single small study to address this question and the overall strength of evidence is very low for no significant differences in operative outcomes.
- KQ2: There is limited evidence from a single small study to address this question although no significant differences were found. The overall strength of evidence is very low for all reported outcomes.
- KQ3: There is no evidence to address this key question.
- KQ4: Robotic and open ileovesicostomy had similar surgical outcomes in one comparative cohort study. Total inpatient costs were significantly higher in the robotic group, primarily due to the higher operating room supply costs. This single study was limited by both small sample size and observational design and the overall strength of evidence is very low on economic outcomes.

Liver Resection

A single retrospective cohort study (n=32) of poor quality compared robotic and laparoscopic liver resection for removal of liver tumors. This study was rated using a standard CEbP tool.

- KQ1: Very low strength of evidence suggests that there were no significant differences between surgical modalities for liver resection. However, these findings are limited by the poor quality of the only study that evaluated these outcomes.
- KQ2: The strength of the evidence on complications arising from robotic and laparoscopic liver resection is very low. These findings are limited by the absence of statistical comparisons between groups.
- KQ3: No evidence was identified that addressed this key question.
- KQ4: No evidence was identified that addressed this key question.

Lung Surgery

There were two comparative studies addressing robotic lung surgery, which were quality rated using the standard CEbP tool. One poor quality study compared robotic thoracoscopic resection to open sternotomy for the treatment of mediastinal tumors. Another study was a fair quality retrospective cohort study that compared robotic lobectomy to open lobectomy for the treatment of lung cancer.

- KQ1: The strength of evidence comparing robotic and open median sternotomy is low for all reported outcomes. The robotic procedure may have had benefits over the open procedure, including less post-operative pain and higher QoL scores (Balduyck 2010). Additionally, the strength of evidence comparing robotic lobectomy to the open procedure is low for all outcomes, but suggests that robotic lobectomy was associated with shorter LOS, longer operating times, and lower lymph node yield than in the open surgical group (Veronesi 2010).
- KQ2: The strength of the evidence on complications arising from robotic and open lung surgery is low, but consistently reports that the incidence of complications was similar between surgical modalities.
- KQ3: There is low strength of evidence suggesting that robotic lobectomy had differential efficacy depending on the surgeon's level of experience. These findings are primarily limited by small sample size and observational study design.
- KQ4: There is mixed evidence on the costs of robotic lung surgery relative to open lung surgery. Both of the identified studies possess significant limitations that prohibit conclusions on this key question. The strength of evidence on economic outcomes is low.

Myomectomy

A SR identified three studies comparing robotic to either laparoscopic or open myomectomy for the treatment of leiomyomata. The authors of the SR did not report the quality assessment ratings of these studies. One subsequent poor quality study comparing robotic to open myomectomy was identified. The study was rated using a standard CEbP tool.

- KQ1: Low strength of evidence indicates that robotic myomectomy was associated with lower blood loss and shorter LOS, compared to both open and laparoscopic groups, but longer duration of surgery when compared to the open approach. Operative times were similar for robotic compared with laparoscopic approaches. Despite methodological limitations of retrospective design and relatively small samples, these results were consistent across studies.

- KQ2: The strength of the evidence regarding similar complications arising from robotic, laparoscopic and open myomectomy is low. Although (2010) Ascher reports similar rates of complications between groups, the study also cites lower febrile morbidity in the robotic group. However, differences in post-operative monitoring may account for this finding, as the robotic group self-reported fever.

- KQ3: No evidence was identified that addressed this key question.

- KQ4: There is low strength of evidence that robotic myomectomy was associated with higher total hospital costs than both laparoscopic and open myomectomy. However, these findings are limited by the clinical evidence that informed this economic analysis. In particular, the underlying clinical outcomes were obtained by a retrospective study that did not perform any follow-up of patients, which may greatly affect estimates of costs associated with complications.

Oropharyngeal Surgery

Four retrospective cohort studies were identified which compared robotic, open, or laparoscopic approaches to pancreatectomy. All were rated as poor quality. Studies were rated using a standard CEbP tool.

- KQ1: The strength of evidence if very low that robotic oropharyngeal salvage surgery for recurrent neoplasm was not significantly different for LOS and gastrostomy tube dependence at six months compared to open surgery.

- KQ2: There is very low strength of evidence regarding complications of robotic compared with open oropharyngeal surgery.

- KQ3: No evidence was identified that addressed this key question.

- KQ4: No evidence was identified that addressed this key question.

Pancreatectomy

Four retrospective cohort studies were identified which compared robotic, open, or laparoscopic approaches to pancreatectomy. All were rated as poor quality. Studies were rated using a standard CEbP tool.

- KQ1: There is low-strength of evidence that robotic pancreatectomy was associated with longer operative times compared to laparoscopic and open surgical approaches. The strength of evidence is very low that LOS and EBL were decreased for robotic versus

open procedures. There is very low strength of evidence of mixed results for blood loss, but similar LOS, compared to laparoscopic procedures.

- KQ2: There is low strength of evidence that robotic surgery resulted in mixed findings for complications compared to open and laparascopic approaches.
- KQ3: No evidence was identified that addressed this key question.
- KQ4: There is an overall low strength of evidence that robotic, open and laparoscopic pancreatectomy had similar costs after adjustment for amortized equipment costs.

Pyeloplasty

One SR was identified that included four studies comparing robotic to laparoscopic pyeloplasty for the treatment of ureteropelvic junction obstruction. The authors of the SR did not report the quality assessment ratings of these studies. One subsequent retrospective cohort study of poor quality addressed the same interventions. The study was rated using a standard CEbP tool.

- KQ1: There is a low strength of evidence that robotic pyeloplasty and laparoscopic pyeloplasty achieve similar outcomes in terms of EBL, LOS, surgical success rate, post-operative pain, and renal function. Mixed evidence suggests that laparoscopic surgery may have yielded shorter operating times than robotic procedures. Although the strength of the evidence is low, there is notable consistency across most findings.
- KQ2: The strength of the evidence on complications arising from robotic and laparoscopic pyelplasty procedures is low, but consistently reports that the two surgical approaches are similar in this regard.
- KQ3: No evidence was identified that addressed this key question.
- KQ4: There is low strength of evidence indicating that the cost of robotic pyeloplasty was greater than laparoscopic pyeloplasty based on projected perioperative costs from a single good quality study. These findings are limited by potential bias that may have been introduced if the robotic procedures were the first ones performed by surgeons at the institution.

Rectopexy

One SR identified a single study that compared robotic and laparoscopic rectopexy for the treatment of rectal prolapse. The authors of the SR did not report the quality assessment ratings of these studies. Two additional subsequent comparative studies were identified, which were quality rated using the standard CEbP tool. One was a poor quality retrospective cohort study that compared robotic to laparoscopic rectopexy. The other was a poor quality retrospective cohort study that compared robotic to both laparoscopic and open rectopexy.

- KQ1: Low strength of evidence suggests that robotic rectopexy was associated with longer operating times and higher odds of recurrence of rectal prolapse compared to

open or laparoscopic procedures. These findings are limited by small sample sizes (de Hoog 2009; Wong 2011) and different inclusion criteria between groups (de Hoog 2009).

- KQ2: Low strength of evidence consistently suggests that robotic, laparoscopic and open rectopexy procedures were similar in terms of complication incidence.
- KQ3: There is no evidence to address this key question.
- KQ4: There is low strength of evidence indicating that robotic rectopexy was more expensive than laparoscopic surgery. However, these findings are limited because the details of this cost estimate and how it was formulated were not described.

Roux-en-Y Gastric Bypass

One good quality RCT and three non-randomized studies compared robotic versus laparoscopic Roux-en-Y gastric bypass procedures for the treatment of morbid obesity. The authors of the SR did not report the quality assessment ratings of these three studies. Two subsequent retrospective studies were identified using the same comparative groups. Both were rated as poor quality using a standard CEbP tool. One additional subsequent study of good quality, rated using a standard CEbP tool, was identified which reported the same comparative interventions in a sub-group of morbidly obese patients.

- KQ1: There is moderate strength of evidence that robotic Roux-en-Y gastric bypass was associated with higher odds of operative conversion than laparoscopic gastric bypass, but is similar in terms of operative duration. There is low strength of evidence that robotic Roux-en-Y gastric bypass was associated with shorter ICU and hospital stays than open surgery. The conversions from robotic surgery were primarily to open approach with a few converted to conventional laparoscopic approach. There were no conversions from the laparoscopic primary procedures.
- KQ2: There is low strength of evidence that complications were similar between laparoscopic and robotic procedures. The strength of evidence that complications were similar between open and robotic Roux-en-Y is low.
- KQ3: There is low strength of evidence that robotic Roux-en-Y gastric bypass had shorter operative time than laparoscopic Roux-en-Y, particularly as the degree of obesity increases.
- KQ4: There is low strength of evidence that robotic procedures cost more than laparoscopic gastric bypass.

Sacrocolpopexy

One SR identified a single prospective cohort study which compared robotic to open sacrocolpopexy for the treatment of vaginal or uterine prolapsed. The authors of the SR did not report the quality assessment ratings of this study. Three subsequent studies were identified addressing the same comparative interventions. One RCT was rated fair, the other two small retrospective studies as poor quality using a standard CEbP tool.

- KQ1: Low strength of evidence indicates that robotic and laparoscopic sacrocolpopexy resulted in statistically similar activity limitation and time until return of normal activity level. Findings on perioperative outcomes, such as operating time, LOS, and EBL, and symptom relief, were mixed. Evidence comparing robotic sacrocolpopexy to open surgery was mixed. Although the Geller study (2008) reported in the Reza review (2010) reported shorter LOS, less blood loss, and longer surgical duration among the robotic group, the Patel study (2009) found no significant differences between groups on these outcomes. Given the small size of the Patel study (n=5 in each arm), it was likely underpowered to detect such differences. The strength of evidence comparing robotic sacrocolpopexy to open surgery is very low.

- KQ2: The strength of the evidence on complications arising from robotic, laparoscopic and open sacrocolpopexy is low. Compared to open surgery, robotic surgery was reported as having increased incidence of postoperative fever. Additionally, several studies have found that the incidence of complications was similar between robotic and laparoscopic methods.

- KQ3: No evidence was identified that addressed this key question.

- KQ4: There is low strength of evidence that laparoscopic sacrocolpopexy was associated with lower total healthcare system costs than robotic sacrocolpopexy. These findings may be limited by potential bias in favor of the laparoscopic procedure if surgeons performing robotic procedures had not yet attained complete proficiency. However, this bias may be balanced by the fact that the highest quality analysis, performed in the Paraiso study, did not account for purchase or maintenance of the *da Vinci* system in its cost analysis. There is very low strength of evidence that robotic sacrocolpopexy has higher total charges compared to open procedures.

Splenectomy

One small (n=12) retrospective cohort study was identified comparing robotic to laparoscopic splenectomy for treatment of hematologic disorders. This study was rated as poor quality using a standard CEbP tool.

- KQ1: There is very low strength of evidence that laparoscopic splenectomy was associated with shorter operating time as compared to robotic splenectomy. Additionally, there is low strength of evidence that LOS and EBL were similar between surgical modalities.

- KQ2: The strength of the evidence on complications arising from robotic and laparoscopic splenectomy is very low due to retrospective study design and small sample size. However, the evidence suggests that the incidence and severity of complications was similar between the two approaches.

- KQ3: No evidence was identified that addressed this key question.

- KQ4: There is very low strength of evidence that robotic splenectomy incurred higher costs than laparoscopic splenectomy, though the analysis relied primarily on itemized charges reported by a single institution's billing department.

Thymectomy

The MEDLINE® search identified two studies comparing robotic and either thoracoscopic or open thymectomy for treatment of myasthenia gravis. Both of these studies were retrospective cohort studies that were rated as poor quality using a standard CEbP tool.

- KQ1: The overall strength of evidence is low that robotic thymectomy was associated with clinical improvement at follow-up and shorter LOS as compared to thoracoscopic or open thymectomy. There is low strength of evidence for longer operative times for robotic versus open procedures. There is low strength of evidence that EBL was similar among all treatment groups.

- KQ2: The strength of the evidence on complications arising from robotic, endoscopic and open thymectomy is low. However, this limited evidence suggests that the incidence and severity of complications may have been similar among all three surgical approaches.

- KQ3: No evidence was identified that addressed this key question.

- KQ4: No evidence was identified that addressed this key question.

Thyroidectomy

The MEDLINE® search identified five studies which compared robotic to conventional endoscopic or open approach to thyroidectomy for the treatment of thyroid cancer, goiter, or hyperthyroidism. One of the studies was prospective and quality rated as poor. The other four studies were retrospective and quality rated as fair (one study) of poor (three studies). All studies were rated using a standard CEbP tool.

- KQ1: There is low strength of evidence that robotic thyroidectomy and endoscopic or open thyroidectomy were similar in terms of most outcomes. While there was a quantity of research for this procedure, most of the studies were poor and subject to substantial biases. Operative times were longer for robotic procedures than open procedures, though evidence comparing operative times in robotic thyroidectomy to endoscopic thyroidectomy was mixed. However, in terms of patient-important outcomes (ease of swallowing, cosmetic satisfaction), robotic surgery appeared to yield more favorable outcomes. However, these outcomes were only assessed by one moderate quality study (Lee 2011b) and future studies may further inform these outcomes.

- KQ2: The strength of the evidence on complications arising from robotic, endoscopic and open thyroidectomy is low. However, consistent evidence suggests that the

incidence and severity of complications were similar between all three surgical approaches.

- KQ3: The strength of the evidence is very low that robotic thyroidectomy was associated with shorter learning curves than endoscopic thyroidectomy. Given that the same surgeon was concurrently performing both procedures and the robotic group was more likely to have benign lesions and less likely to have lymph node dissection, these findings are substantially vulnerable to potential biases.

- KQ4: The strength of evidence is very low that higher costs are associated with robotic surgery compared to endoscopic thyroidectomy.

Trachelectomy

The MEDLINE® search identified one small retrospective cohort comparing robotic and open trachelectomy. This study was rated as good quality using a standard CEbP tool.

- KQ1: There is very low strength of evidence that robotic-assisted trachelectomy resulted in shorter LOS and reduced EBL when compared to the open approach.

- KQ2: There is very low strength of evidence that the postoperative morbidities (fever, UTI, cervical stenosis, menstrual bleeding) of robotic and open trachelectomy were similar. However, there was a significantly higher rate of conversion to hysterectomy in the robotic group.

- KQ3: No evidence was identified that addressed this key question.

- KQ4: No evidence was identified that addressed this key question.

Vesico-vaginal Fistula

The MEDLINE® search identified one small retrospective cohort comparing robotic and laparotomy vesico-vaginal fistula (VVF) repair. This study was rated as poor quality using a standard CEbP tool.

- KQ1: The strength of evidence for all comparators and outcomes is very low. Although the strength of evidence on the comparative effectiveness of robotic VVF repair is very low, robotic VVF repair was associated with short hospital stays and lower blood loss compared to open VVF repair. No differences in operating time or surgical success rate were reported. However, these findings are limited to a single study, itself limited by retrospective design, small sample size, and reliance on surrogate outcomes. Patient-important outcomes (e.g., time to return to normal activity) were not measured.

- KQ2: The strength of the evidence on complications arising from robotic and open VVF repair is very low, but suggests that the incidence and severity of complications was similar between the two approaches.

- KQ3: No evidence was identified that addressed this key question.

- KQ4: No evidence was identified that addressed this key question.

Guidelines

Fourteen guidelines addressed the use of robotic assistance in nine procedures. All except four recommendations are based primarily on whether the procedure is recommended for the indication rather than the specific use of robotic technology. In other words, if the laparoscopic procedure is recommended, then the robotic approach is also included.

Recommendations regarding the use of robotic assistance in prostatectomy varied according to surgical indication. In the treatment of prostate cancer and benign prostatic hyperplasia, four guidelines (NICE 2008b; Spanish NHS 2008, NCCN 2012a; AUA 2010) recommended robotic surgery along with laparoscopic while one recommended against it (NICE 2006). Prostatectomy for benign prostatic obstruction with or without robotic assistance is not recommended.

Two guidelines (EAU 2011; NICE 2009) recommend laparoscopic cystectomy for bladder cancer, with or without robotic assistance. Six guidelines recommend the use of robotic techniques in esophagogastrectomy (NCCN 2011), radical and partial nephrectomy (NCCN 2012b), pyeloplasty (NICE 2009b), fundoplication (SAGES 2010), pelvic lymph node dissection (NCCN 2012), and a weak recommendation for myotomy (SAGES 2011). One guideline recommends against robotic assisted coronary artery bypass grafting procedures (NICE 2008c).

Policy Considerations

At the direction of WA HTA, this review searched for Medicare, Aetna, Regence, and Group Health policies addressing robotic assisted surgery. Two of these payers, Medicare and Regence Blue Cross Blue Shield, have policies allowing the use of robotic assisted surgery, but not providing additional reimbursement for this technique. Reimbursement is based on the primary or underlying surgical procedure performed. Medicare has not issued local or national coverage determinations outlining clinical criteria for use of robotic assisted surgery. Similarly, none of the private payers searched have set forth clinical coverage criteria for robotic assisted surgery.

Overall Summary

This report presents evidence about the application of robotic assisted surgery for over 25 different individual types of procedures. There was a lack of evidence to answer all key questions for each procedure. However, in general there is low to moderate strength of evidence that robotic assisted procedures are associated with outcomes such as shorter hospital stays, reduced blood loss and transfusion for several procedures. Operative times using robotic assistance are generally longer than for conventional surgeries. There is a general lack of study of patient-centered outcomes such as quality of life and longer term outcomes such as survival. Many studies are hampered by small sample sizes, retrospective nature of data collection and analysis, dissimilarities of control groups, and inadequate control of potential confounders.

Many studies reported no or few types of adverse events and harms regarding the use of robotic assistance for these procedures and the overall strength of evidence for harms was insufficient to low for most procedures. Where it was reported, robotic assisted surgery generally had similar complication rates to laparoscopic procedures or to open procedures.

There were insufficient data to address the question of differential safety or efficacy of robotic assisted procedures for subgroups of patients by gender, age, patient characteristics or comorbidities, or type of payer for nearly all procedures. Where it was studied there were data indicating that there is a “learning curve” for use of robotic equipment and that some intermediate outcomes improved with increasing levels of experience.

Most of the included economic evaluations offered insufficient or low overall strength of evidence to address economic questions. In nearly all cases, the costs of robotic procedures were higher than comparable laparoscopic or open procedures. Cost-effectiveness studies are hampered by lack of full information on all relevant outcomes and insufficient length of follow up to determine long term benefits and safety.

Background

Over the past 20 years, robotic surgical systems have been developed to assist surgeons with performing minimally-invasive procedures. Designed to increase surgical precision and minimize complications, these systems may afford better outcomes for patients than traditional laparoscopic surgery or open surgery.

In the past, the two primary robotic surgical systems in development were the *da Vinci* system (Intuitive Surgical, Inc., Sunnyvale, California, USA) and the ZEUS robot (formerly of Computer Motion, Inc.). However, since the 2003 acquisition of Computer Motion by Intuitive Surgical, the *da Vinci* system has been the only robotic surgical system on the market (Ho [CADTH] 2011). In 2000, the *da Vinci* robot was approved by the Food and Drug Administration (FDA) for general laparoscopic surgery. Numerous other indications for the *da Vinci* system have since been approved by the FDA, including urological procedures, gynecologic laparoscopic procedures, general thoracoscopic procedures, and others.

Clinical and epidemiological overview

Radical prostatectomy, hysterectomy, nephrectomy, and cardiac valve repair are among the most common applications of the *da Vinci* surgical system. While various cancer surgeries are often the primary indications for these procedures, other indications are also common, including benign neoplasms (e.g., uterine fibroids), as well as damaged or defective anatomical features (e.g., valvular heart disease). Background information on these four most common indications is presented in the paragraphs below.

Prostatectomy is typically performed to treat prostate cancer. In 2011, an estimated 240,890 men were diagnosed with prostate cancer in the United States. From 2004 to 2008, the age-adjusted incidence of prostate cancer was estimated to be 156.0 per 100,000 men annually, while an estimated 24.4 per 100,000 men with prostate cancer died each year (National Cancer Institute [NCI] 2011a). For patients in good health, prostatectomy is often recommended as a treatment option for men with prostate cancer. Each year, approximately 158,000 prostatectomy procedures are performed in the US (CDC 2009). Of these, three in four prostatectomies are performed using the *da Vinci* robot (Intuitive Surgical, Inc. 2012).

Among reproductive-aged women in the US, hysterectomy is the second most frequent major surgical procedure. The Centers for Disease Control (CDC) estimates that approximately 600,000 hysterectomies are performed each year (CDC 2009). Typical indications for hysterectomy include uterine fibroids, endometriosis, uterine prolapse, chronic pelvic pain, and reproductive system cancers (American College of Obstetrics and Gynecology [ACOG] 2011). Although laparotomy is the most common route of hysterectomy, laparoscopic hysterectomy has increased in popularity over the past 20 years (Jacoby 2009).

Kidney cancer is the most frequent indication for nephrectomy. The NCI reports that over the past 65 years, the incidence of kidney cancer has steadily risen (NCI 2011b). In 2011, an estimated 60,920 were diagnosed with cancer of the kidney and renal pelvis, while approximately 4.0 per 100,000 die from these diseases each year (NCI 2011b). Nephrectomy is

the most common treatment modality for kidney cancer, with an estimated 150,000 radical nephrectomies and 39,000 partial nephrectomies performed across the US between 2003 and 2008 (Kim 2011).

Several types of cardiac surgery may be performed using the *da Vinci* robot. Repair of valvular heart diseases (e.g., mitral valve prolapse, mitral regurgitation) make up a substantial proportion of cardiac procedures currently performed robotically. However, other cardiac procedures, such as coronary artery bypass grafting (CABG), are also being performed. The combined burden of mitral regurgitation and mitral valve prolapse is significant, with each occurring in approximately 2% of the population, and approximately 65,000 mitral valve repairs or replacements being performed each year (Curtin 2010).

Technology overview

The *da Vinci* system is designed to improve upon traditional laparoscopic surgery by providing three-dimensional visualization, improved ergonomics, and increased precision. Intuitive Surgical defines the *da Vinci* surgical system by its four main components: the surgeon console, the patient-side cart, the EndoWrist instruments, and the vision system. Surgeons use the computer console during procedures to view the surgical field and control the robotic arms. Three to four robotic arms, which are coupled to the patient-side cart, maneuver under the surgeon's direction. At the console, the surgeon uses EndoWrist surgical instruments that are designed to mimic human wrists by allowing seven degrees of motion. The vision system displays the surgeon's field of view to the operating room team.

Cost information

Both the necessity of intensive surgeon and surgical team training and the financial costs associated with these systems are significant considerations. The *da Vinci* system itself costs $1.0M to $2.3M, depending on options, and disposable instrument costs per procedure range from $1,300 to $2,200 in the United States. An annual service agreement totaling $100K to $170K per year is also required. Surgeons require initial device training from the manufacturer, as well as clinical training and continuing education. Depending on the complexity of the procedure and the surgeon's skill level, the learning curve may be steep and length of the clinical training period may be significant.

Policy context

The promises of minimally invasive surgery have captured the attention of patients, practitioners, and healthcare administrators alike. Faster recovery times and fewer complications would likely translate to shorter hospital stays, which may also help to minimize cost. Whether robotic-assisted surgery provides better outcomes than other minimally invasive techniques are important questions still under research. In 2007, the American Medical Association determined that an additional CPT code for robotic-assisted procedures was not necessary. As such, robotic-assisted procedures are reimbursable at the same rate as non-robotic procedures. Nevertheless, demand for robotic-assisted surgery is rising. Intuitive Surgical reported that 278,000 *da Vinci* procedures were performed in 2010, representing a 35% increase from 2009. An additional 30% increase in the number of procedures was expected

for 2011. Prostatectomy procedures made up approximately one quarter of all robotic procedures performed in 2010, while hysterectomy procedures made up more than one third. As of the first quarter of 2012, 37 *da Vinci* Surgical Systems had been installed in the State of Washington. According to the company, since its first *da Vinci* System shipment, Intuitive Surgical has expanded its installed base to more than 1,500 academic and community hospital sites across the United States, while sustaining growth in excess of 25% annually.

Washington State Agency Data

Robotic-assisted surgeries were identified in claims data using CPT S2900 or ICD9 Procedure 17.4x, which are for identification only and have no direct charge associated. Most procedures were laparoscopic prostatectomies and hysterectomies, identified using ICD9 procedure code 17.42. Charges were captured for the duration of the hospital stay, or for the day of surgery for outpatient procedures.

Note that payment strategies differ between agencies – while Labor and Industry pays 100% of the allowed amount for each claim, Medicaid pays the full allowed amount, or a residual amount when they are a secondary payer to Medicare. Public Employee Benefits (PEB) pays a percentage of the allowed amount on each claim, which can be further reduced by the amount paid by members as a deductible, or by other primary carriers or Medicare. Unless specifically noted otherwise, the amounts in the tables that follow are the actual amounts paid by each agency.

Figure 1. All Agencies, Robotic Assisted Surgery 2007-2010

Robotic Assisted Surgeries	2007	2008	2009	2010	Overall	Overall Average Payment
PEB						
Patients	1	28	142	217	388	
Payments	$15,625	$253,421	$1,610,844	$3,235,319	$5,115,209	$13,184
Medicaid						
Patients	0	16	78	133	227	
Payments	$0	$201,329	$1,398,773	$2,228,764	$3,828,866	$14,875*
L&I						
Patients				2	2	
Payments				$16,866	$16,866	$8,433
All Agencies						
Patients	**1**	**44**	**220**	**352**	**617**	
Payments	**$15,625**	**$454,750**	**$3,009,617**	**$5,480,949**	**$8,960,941**	**$14,523**

* Two outlier surgeries were excluded from the average calculation (each over $250K)

Figure 2a. PEB Robotic Assisted Surgery Totals, 2007-2010 by Procedure Type

Procedure Type (ordered by total payments)	Totals 2007-2010		Averages		Variability		
	Payments	Patients	Per Procedure	Per Procedure (Prime only)	Maximum Paid	Minimum Paid (Prime only)	Std Dev
Prostate	$1,963,137	171	$11,480	$20,297	$82,030	$3,639	$11,270
Gynecological	$1,718,408	136	$12,635	$16,130	$75,940	$4,272	$12,862
Urinary Tract	$561,101	27	$20,782	$27,276	$83,901	$3,839	$19,324
Other	$559,332	29	$19,287	$39,363	$92,396	$12,435	$22,056
Pelvic	$222,435	19	$11,707	$13,377	$24,388	$8,168	$4,423
Combination	$90,796	6	$15,133	$15,133	$19,293	$12,511	$2,928
All Procedures	**$5,115,209**	**388**	**$13,184**	**$21,761**	**$92,396**	**$3,639**	**$14,014**

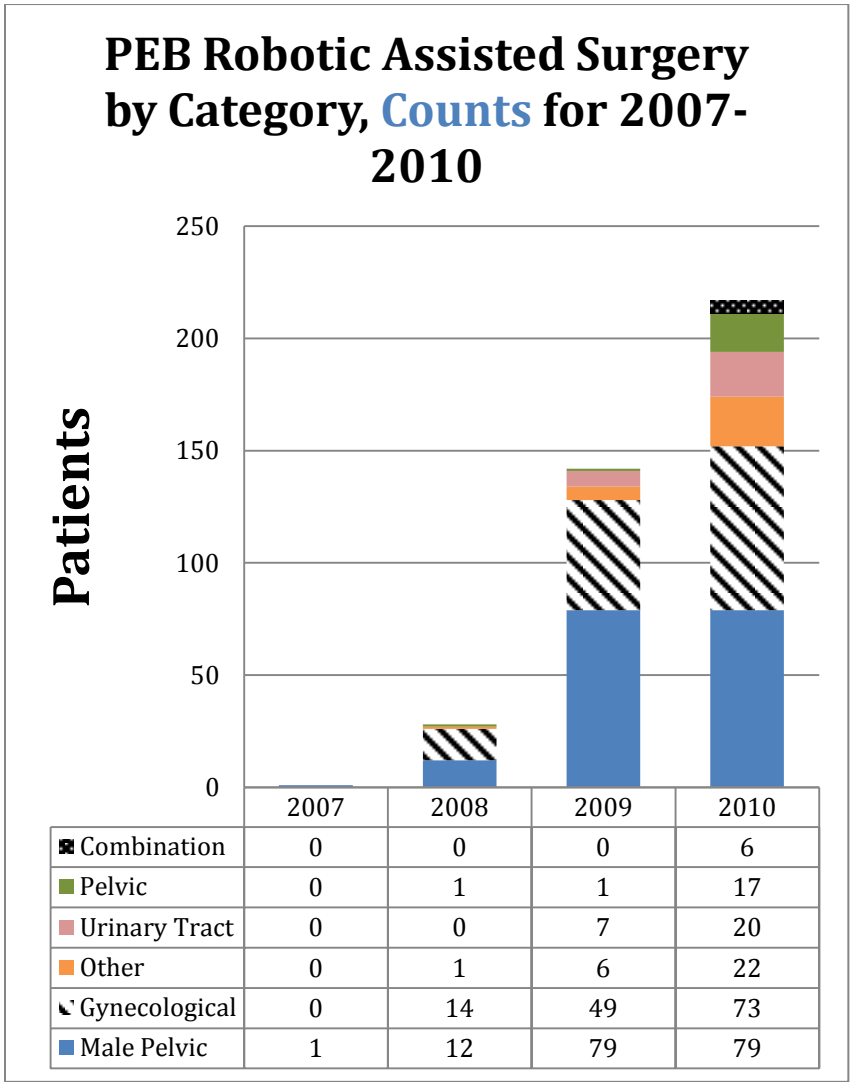
*Other procedures: Adrenal, cardiac, cholescystectomy, digestive, non-prostatic/gynecologic cancers, musculoskeletal, and unidentified

Figure 2b. Medicaid Robotic Assisted Surgery Totals, 2007-2010, by Procedure Type

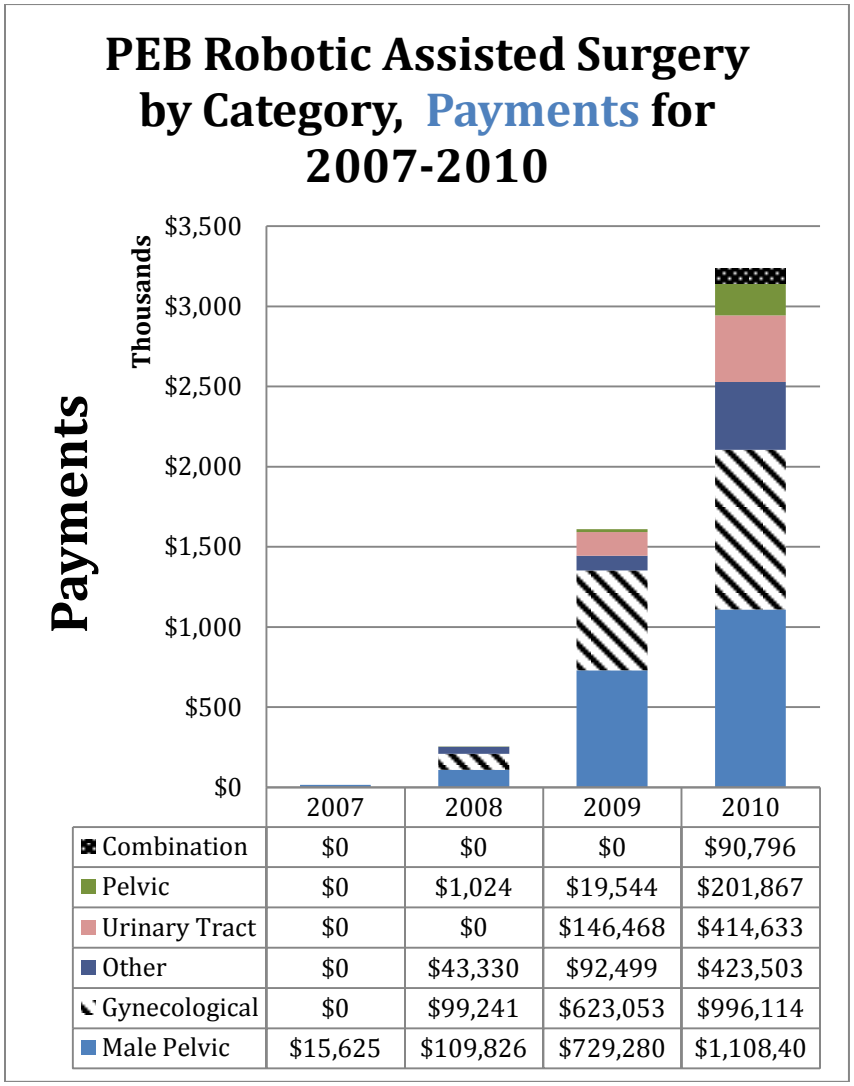
Procedure Type (ordered by total payments)	Totals 2007-2010		Averages		Variability		
	Payments	Patients	Per Procedure	Per Procedure (Non Medicare Crossover)	Maximum Paid	Minimum Paid	Std Dev
Gynecological	$1,512,792	144	$10,506	$13,102	$189,788	$2,148	$21,738
Other*	$1,007,370	22	$45,790	$27,595	$112,068	$493	$69,153
Cardiac	$684,642	16	$42,790	$45,566	$97,671	$1,150	$26,962
Gastro/Chole	$336,479	9	$37,387	$37,387	$112,776	$8,048	$39,115
Urinary Tract	$225,861	21	$10,755	$13,785	$55,542	$2,066	$14,425
Prostate	$61,723	15	$4,115	$10,944	$37,219	$104	$3,936
All Procedures	**$3,828,866**	**227**	**$16,867**	**$19,082**	**$189,788**	**$104**	**$32,419**

*Other procedures included two outliers for payment more than 3 standard deviations from the mean. These were excluded from average payment calculations. Other procedures: Adrenal, thymus, pancreas, breast cancer, tonsillectomy, musculoskeletal and respiratory system.

Figure 3a, 3b. PEB Robotic Assisted Surgery Trends, Payments and Patients, 2007-2010



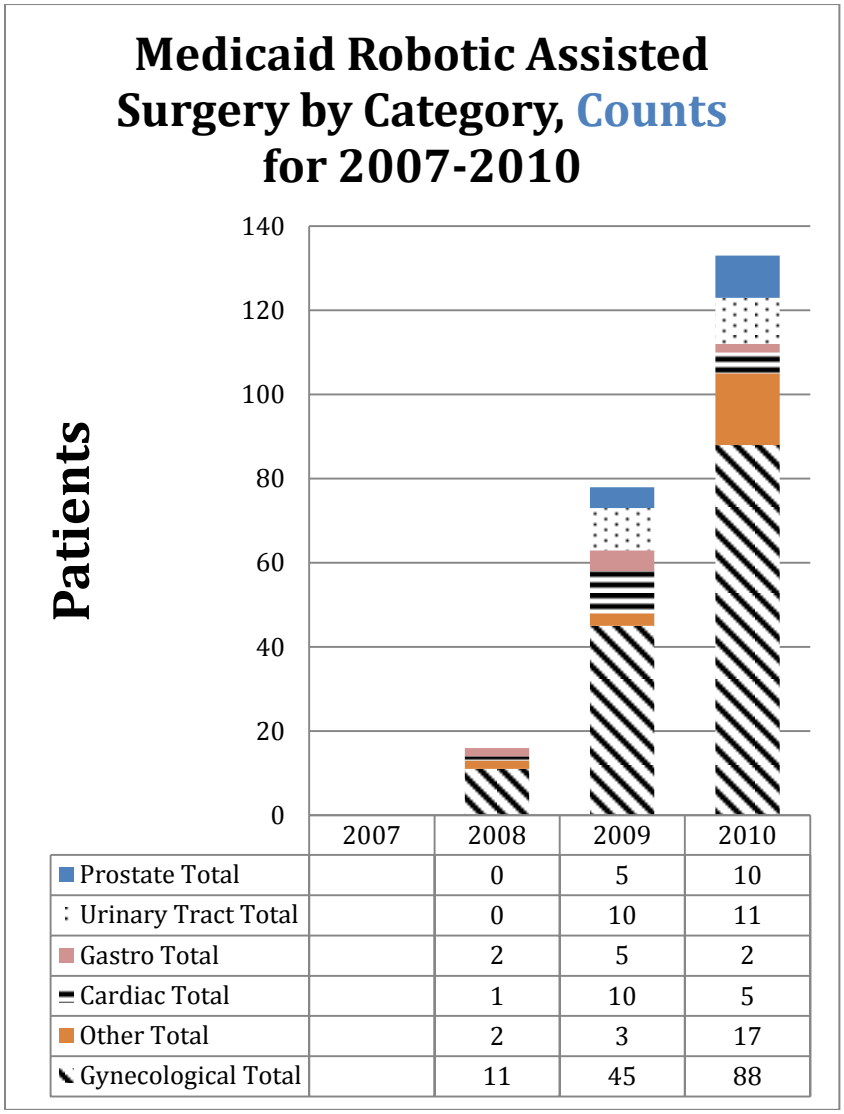
	2007	2008	2009	2010
Combination	0	0	0	6
Pelvic	0	1	1	17
Urinary Tract	0	0	7	20
Other	0	1	6	22
Gynecological	0	14	49	73
Male Pelvic	1	12	79	79



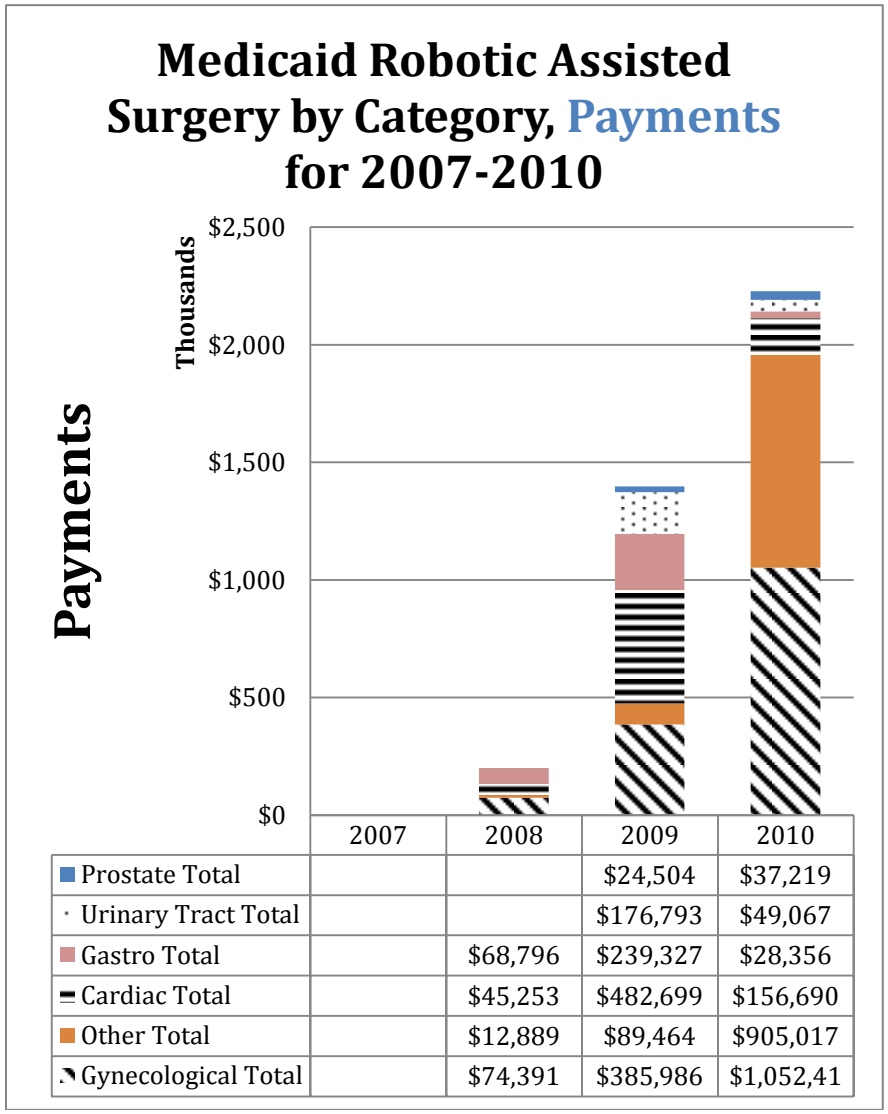
	2007	2008	2009	2010
Combination	$0	$0	$0	$90,796
Pelvic	$0	$1,024	$19,544	$201,867
Urinary Tract	$0	$0	$146,468	$414,633
Other	$0	$43,330	$92,499	$423,503
Gynecological	$0	$99,241	$623,053	$996,114
Male Pelvic	$15,625	$109,826	$729,280	$1,108,40

*Other procedures: Adrenal, cardiac, cholescystectomy, digestive, non-prostatic/gynecologic cancers, musculoskeletal, and unidentified

Figure 3c, 3d. Medicaid Robotic Assisted Surgery Trends, Payments and Patients, 2007-2010



	2007	2008	2009	2010
Prostate Total		0	5	10
Urinary Tract Total		0	10	11
Gastro Total		2	5	2
Cardiac Total		1	10	5
Other Total		2	3	17
Gynecological Total		11	45	88



	2007	2008	2009	2010
Prostate Total			$24,504	$37,219
Urinary Tract Total			$176,793	$49,067
Gastro Total		$68,796	$239,327	$28,356
Cardiac Total		$45,253	$482,699	$156,690
Other Total		$12,889	$89,464	$905,017
Gynecological Total		$74,391	$385,986	$1,052,41

Other procedures: Adrenal, thymus, pancreas, breast cancer, tonsillectomy, musculoskeletal and respiratory system procedures

Related Medical Codes

Code	Description	Type
S2900	Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)	CPT
17.41	Open robotic assisted procedure	ICD9 Procedure
17.42	Laparoscopic robotic assisted procedure	ICD9 Procedure
17.43	Percutaneous robotic assisted procedure	ICD9 Procedure
17.44	Endoscopic robotic assisted procedure	ICD9 Procedure
17.45	Thoracoscopic robotic assisted procedure	ICD9 Procedure
17.49	Other and unspecified robotic assisted procedure	ICD9 Procedure

PICO

Population: Adults with planned surgeries that could be performed with the help of a robotic-assisted surgery device (e.g., prostatectomy, hysterectomy, nephrectomy, coronary bypass, coronary valve replacement) under any diagnosis, including cancer.

Intervention: Surgery with the assistance of robotic control, any diagnosis.

Comparator: Surgeries of the same type, performed open or laparoscopic, without robotic assistance.

Outcomes: Hospital length of stay, health care resource utilization, recovery of activities of daily living, quality of life, overall mortality, disease specific mortality or survival, cancer recurrence, adverse events (e.g. morbidity, mortality, reoperation, complication rates, increased bleeding), healing time, cost, cost effectiveness.

Key Questions

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes? Include consideration of short and long-term outcomes, and assessment of clinically meaningful outcomes.

KQ 2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches? Include consideration of morbidity, mortality, reoperation, excess bleeding, and extended hospital stay.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations? Including consideration of:

a. Gender

b. Age

c. Psychological or psychosocial co-morbidities

d. Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes and high BMI

e. Provider type, experience, or other characteristics and setting (including facility/ team experience)

f. Payer / beneficiary type including worker's compensation, Medicaid, state employees

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Methods

A systematic review using best evidence methodology for each procedure was used to search and summarize evidence for key questions #1 through #3 as outlined below.

- Complete a search of the Medicaid Evidence-based Decisions Project primary evidence sources;
- Existing good quality systematic reviews (SRs) and technology assessments (TAs) were summarized by procedure for each key question;
- If there were two or more comparable SRs or TAs identified and one was more recent, of better quality, or more comprehensive, then the other review(s) were excluded;
- An additional search of the MEDLINE® database was completed to identify subsequently published studies. Individual studies published after the search dates of the last good quality review were appraised and synthesized with the results of the good quality systematic reviews; and
- If there were no good quality reviews identified for a procedure, a search, an appraisal, and a summary of primary individual studies were completed for the last 10 years (January 2002 to January 2012).

Evidence

Search strategy

For this WA HTA report, a search was conducted to identify published SRs and individual studies (from January 2002 to February Week 1 2012) in MEDLINE®. The detailed search strategy is provided in Appendix A. A list of excluded studies with reasons for exclusion is provided in Appendix B. An additional search using the Medicaid Evidence-based Decisions (MED) Project primary sources was completed to identify systematic reviews and technology assessments. The primary sources searched included: Cochrane Library (Wiley Interscience), UK National Institute for Health and Clinical Excellence (NICE), Blue Cross/Blue Shield Health Technology Assessment (HTA) program, Veterans Administration TA program, BMJ Clinical Evidence, the Canadian Agency for Drugs and Technologies in Health (CADTH), and the Agency for Health Research and Quality (AHRQ).

Inclusion Criteria

Articles were included if they were:

- Published, peer reviewed, and English-language articles;
- Systematic reviews, health technology assessments, meta-analyses, randomized controlled trials (RCTs), controlled clinical trials or comparative observational studies;
- Published after 2002, regardless of the presence of good -quality reviews, if they address sub-populations or cost; and
- Compared a robotic-assisted procedure to the same type of procedure performed without robotic assistance, either by conventional laparoscopy or open laparotomy.

For key question #4, all relevant economic evaluations of robotic surgery published within the past 10 years were included.

Exclusion Criteria

Articles were excluded if they:

- Were not comparative (e.g., case report, narrative review, editorial, etc.);
- Addressed only pediatric procedures, or if adult surgical outcomes were aggregated with pediatric surgical outcomes;
- Were published prior to 2002, or prior to the end search date of the most relevant review being used to summarize the procedure. A matrix outlining the reviews and search dates for each procedure is provided in Appendix C;
- Compared obsolete robotic systems;
- Were robotic-assisted procedures that were not performed entirely by robotic surgery; or
- Used robotic assistance not designed to improve upon procedures otherwise performed by laparoscopy or laparotomy.

Quality Assessment - Evidence

The methodological quality of the included studies was assessed using standard instruments developed and adapted by the Center for Evidence-based Policy (CEbP) and the MED Project that are modifications of the systems in use by NICE and SIGN (NICE 2009; SIGN 2009). All studies were assessed by two independent and experienced raters. In cases where there was not agreement about the quality of the study or guideline the disagreement was resolved by conference or the use of a third rater. The evaluation checklists for individual studies are provided in Appendix G.

The overall strength of evidence was rated using a modified version of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system (Guyatt 2008). Each study was assigned a rating of good, fair, poor, based on its adherence to recommended methods and potential for biases. In brief, good quality SRs included a clearly focused question,

a literature search that was sufficiently rigorous to identify all relevant studies, criteria used to select studies for inclusion (e.g., RCTs) and assess study quality, and assessments of heterogeneity to determine if a meta-analysis would be appropriate. Good quality RCTs clearly described the population, setting, intervention and comparison groups; randomly allocated patients to study groups; concealed allocation; had low dropout rates; and reported intention-to-treat analyses. Good quality SRs and RCTs also had low potential for bias from conflicts of interest and funding source. Fair quality SRs and RCTs had incomplete information about methods that might mask important limitations. Poor quality SRs and RCTs had clear flaws that could introduce significant bias.

A summary judgment for the overall quality of evidence was assigned to each key question and outcome (Guyatt 2008). The GRADE system defines the quality of a body of evidence for an outcome in the following manner:

- High: Further research is *very unlikely* to change our confidence in the estimate of effect. Typical sets of studies would be large RCTs without serious limitations.
- Moderate: Further research is *likely* to have an important impact on our confidence in the estimate of effect and may change the estimate. Typical sets of studies would be RCTs with some limitations or well-performed observational studies with additional strengths that guard against potential bias and have large estimates of effects.
- Low: Further research is *very likely* to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Typical sets of studies would be RCTs with very serious limitations or observational studies without special strengths.
- Very low: Any estimate of effect is *very uncertain.* Typical sets of studies would be observational studies with very serious limitations and outcomes where there is very little evidence.

Quality Assessment – Economic studies

The methodological quality of the studies was assessed using a standard instrument developed and adapted by the Center for Evidence-based Policy and the MED Project that are modifications of the British Medical Journal (Drummond 1996), the Consensus on Health Economic Criteria list (Evers 2005), and the NICE economic evaluation checklist (NICE 2009). In brief, good quality economic evaluations include a well described research question with economic importance and detailed methods to estimate the effectiveness and costs of the intervention. A sensitivity analysis is provided for all important variables and the choice and values of variables are justified. Good quality economic evaluations also have low potential for bias from conflicts of interest and funding sources. Fair quality economic evaluations have incomplete information about methods to estimate the effectiveness and costs of the intervention. The sensitivity analysis may not consider one or more important variables, and the choice and values of variables are not completely justified. All of these factors might mask important study limitations. Poor quality economic evaluations have clear flaws that could

introduce significant bias. These could include significant conflict of interest, lack of sensitivity analysis, or lack of justification for choice of values and variables. All studies were assessed by two independent and experienced raters. In cases where there was not agreement about the quality of the study the disagreement was resolved by conference or the use of a third rater. The economic evaluation checklist is provided in Appendix G.

Guidelines

Search Strategy

A search for relevant clinical practice guidelines (CPGs) was conducted, using the following sources: the National Guidelines Clearinghouse database, the Institute for Clinical Systems Improvement (ICSI), the Scottish Intercollegiate Guidelines Network (SIGN), the National Institute for Health and Clinical Excellence (NICE), the Veterans Administration/Department of Defense (VA/DOD) guidelines, US Preventive Services Task Force (USPSTF), Australian National Health and Medical Research Council, New Zealand Guidelines Group, and the Center for Disease Control and Prevention (CDC). Guidelines from specialty organizations were also searched including the following: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), Society of Gynecologic Oncology, American Urological Association (AUA), American Academy of Orthopedic Surgeons, American Academy of Otolaryngology, American Association of Neurological Surgeons, American College of Obstetricians and Gynecologists, American Society of Colon and Rectal Surgeons, Society of Thoracic Surgeons, American Society of Nephrology, American College of Cardiology, American College of Surgeons, American Association of Endocrine Surgeons, American Association for the Study of Liver Diseases, American Gastroenterological Association. Included guidelines were limited to those published after 2006.

Quality Assessment

The methodological quality of the guidelines was assessed using an instrument (Appendix G) adapted from the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration (AGREE Next Steps Consortium 2009). The guidelines were rated by two individuals. A third rater was used to obtain consensus if there were disagreements. Each guideline was assigned a rating of good, fair, poor, based on its adherence to recommended methods and potential for biases. A guideline rated as good quality fulfilled all or most of the criteria. A fair quality guideline fulfilled some of the criteria and those criteria not fulfilled were thought unlikely to alter the recommendations. If no or few of the criteria were met, the guideline was rated as poor quality.

Policies

At the direction of the WA HTA program, select payer policies were searched and summarized. Aetna, Regence Blue Cross Blue Shield, Group Health, and Medicare National and Local Coverage Determinations were searched using the payers' websites.

Findings

For the key questions, the core sources search found 107 SRs and TAs, of which 5 met inclusion criteria. The MEDLINE® search retrieved 537 citations, of which 54 articles were included. An additional 223 studies were submitted during the public comment period for this report. Of these, 20 were found eligible for inclusion (19 cohort studies and one economic analysis). A detailed list of excluded studies and their reasons for exclusion is found in Appendix B. All included studies are detailed in the evidence tables included in Appendix D.

A best evidence review was undertaken for all procedures. The good quality, Ho [CADTH] 2011 Technology Assessment, was used as the primary evidence base for hysterectomy, prostatectomy, nephrectomy, and all cardiac surgeries. This TA provided pooled meta-analysis as well as subanalyses by study design and study quality. No RCT's were identified for the specified populations in this technology assessment; all studies were non-randomized prospective or retrospective comparisons. Updated studies of these procedures, identified from the MEDLINE® search that were published after August 2011, were included in this report.

Prostatectomy

There were 55 prostatectomy studies identified comparing robotic surgery with either open or laparoscopic surgery, which addressed the clinical key questions. There were 51 studies identified in the systematic review selected as the sole source of evidence for this procedure Ho [CADTH] (2011) TA. Study quality was assessed as being high in one study, good in six studies, fair to good in 35 studies, poor to fair in eight studies, and poor in one study.[2] An additional four studies were identified updating this TA which were quality rated using the standard CEbP tool. One study was quality rated as good, one as fair, and two as poor.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Ho [CADTH] (2011) TA Results

Patients' baseline characteristics across studies were not summarized with the exception of tumor grade. Most of the prostatectomy studies included men with prostate cancer localized to the prostate gland (pathological category pT1 and pT2). Patients who have extension of their cancer beyond the prostate gland are categorized either as pT3 (extraprostatic extension), or as pT4 (extraprostatic extension with invasion to the rectum and surrounding structures).

[2] CADTH describes their quality assessment tool as a modified version of Hailey et al.'s. Studies are rated on a scale of A to E, where A indicates high quality with a high degree of confidence in study findings; B indicates good quality with some uncertainty about the study findings; C indicates fair to good quality with some limitations that should be considered in any implementation of the study findings; D indicates poor to fair quality with substantial limitations in the study findings; which should be used cautiously; and E indicates poor quality with unacceptable uncertainty in the study findings.

Common study outcomes particular to this procedure included sexual function (defined as the ability to maintain an erection sufficient for intercourse with or without the use of oral phosphodiestepochse-5 inhibitors) and continence (defined in most studies as no urine leaks or leaks less than once per week).

Many of the meta-analyses performed were associated with high (>50%) I^2 and chi^2 values, indicating statistically significant heterogeneity among studies. Relevant potential sources of heterogeneity were investigated for correlation with study outcomes. Subgroup and sensitivity analyses based on study design and study quality were explored to identify systematic variations. Tables 1 and 2 present the findings of these analyses.

Robotic-assisted radical prostatectomy (RARP) compared with open radical prostatectomy (ORP):

The meta-analysis results of the studies pertinent to this comparison favored RARP and are summarized below (WMD= weighted mean difference):

- Shorter length of hospital stay (WMD −1.54 days, 95% CI −2.13 to −0.94);
- Reduction in positive margin rate in pT2 patients (RR 0.6, 95% CI 0.44 to 0.83). The results of this comparison in pT3 patients and in two trials that did not report pT2 and pT3 subclasses, was inconclusive;
- Reduction in the extent of blood loss (WMD −470.26 mL, 95% CI −587.98 to −352.53);
- Reduced risk of red blood cell transfusion (RR 0.20, 95% CI 0.14 to 0.30);
- Urinary continence after 12 months (RR 1.06, 95% CI 1.02 to 1.10); and
- Likelihood of sexual function after 12 months (RR 1.55, 95% CI 1.20 to 1.99).

However, the meta-analysis also found that RARP was associated with longer operative duration than ORP (WMD 37.74 min, 95% CI 17.13 to 58.34).

Results of the analysis based on study design and study quality found:

- Three out of five meta-analyses (pooled meta-analysis, prospective studies, moderate to low quality studies) showed a significant increase in operative time for the robotic group. However, they all reported significant heterogeneity between studies.
- All five meta-analyses showed a consistent significant reduction in hospital stay favoring the robotic surgery group. However, they all reported significant heterogeneity between studies.
- Inconsistent results were reported for incidence of complications. The report meta-analysis, retrospective studies, and the high or good quality studies did not show a significant difference.

- All five meta-analyses showed a significant reduction for blood loss and incidence of transfusion in favor of the robotic surgery group. However, most of them reported significant heterogeneity between studies.

Hospital stay, positive margin rate, incidence of transfusion and blood loss outcomes did not change between the pooled meta-analysis results and the high or good quality and moderate or low quality studies.

Table 4. RARP Compared with ORP[3]

Outcome	Pooled MA (Report Text Results)	Retrospective Studies	Prospective Studies	High to Good Quality Studies	Moderate to Low Quality Studies
Operative Time (minutes)	WMD 37.74* [17.13, 58.34] 19 studies	WMD 20.09*, NS [-16.27, 56.45] 10 studies	WMD 61.38* [33.66, 89.10] 6 studies	WMD -8.90, NS [-27.33, 9.53] 1 study	WMD 40.37* [19.20, 61.54] 18 studies
Hospital Stay (days)	WMD -1.54* [-2.13, -0.94] 19 studies	WMD -1.22* [-1.80, -0.63] 10 studies	WMD -1.78* [-3.23, -0.34] 7 studies	WMD -3.32* [-4.44, -2.21] 2 studies	WMD -1.24* [-1.66, -0.83] 17 studies
Positive margin rate (all)	RR 1.04*, NS [0.80, 1.34] 20 studies	RR 0.97*, NS [0.68, 1.39] 13 studies	RR 1.15*, NS [0.77, 1.70] 7 studies	RR 1.04*, NS [0.64, 1.70] 6 studies	RR 1.03*, NS [0.75, 1.41] 14 studies
Blood Loss (mL)	WMD -470.26* [-587.98, -352.53] 21 studies	WMD -452.26* [-577.54, -326.98] 10 studies	WMD -443.99* [-573.04, -314.93] 8 studies	WMD -406.58*, NS [-630.54, 182.62] 3 studies	WMD -480.30* [-601.74, -358.86] 18 studies
Incidence of transfusion	RR 0.20* [0.14, 0.30] 18 studies	RR 0.17 [0.09, 0.35] 7 studies	RR 0.18* [0.09, 0.36] 9 studies	RR 0.36 [0.20, 0.66] 3 studies	RR 0.17* [0.11, 0.27] 15 studies
Urinary incontinence (12 months)	RR 1.06 [1.02, 1.10] 8 studies	RR 1.01, NS [0.96, 1.08] 2 studies	RR 1.11 [1.05, 1.18] 3 studies	RR 1.07*, NS [0.98, 1.17] 3 studies	RR 1.05, NS [1.00, 1.11] 5 studies
Sexual competence	RR 1.55* [1.20, 1.99] 7 studies	RR 1.75*, NS [0.43, 7.08] 1 study	RR 1.84 [1.49, 2.28] 3 studies	RR 1.48*, NS [0.98, 2.23] 3 studies	RR 1.56 [1.28, 1.89] 4 studies
Incidence of complications	RR 0.73*, NS [0.54, 1.00] 15 studies	RR 0.63, NS [0.35, 1.14] 6 studies	RR 0.61* [0.45, 0.83] 7 studies	RR 0.93, NS [0.52, 1.65] 4 studies	RR 0.66* [0.48, 0.92] 11 studies

<u>Robotic-assisted radical prostatectomy (RARP) compared with laparoscopic radical prostatectomy (LPR):</u>

The meta-analysis results of the studies pertinent to this comparison favored RARP or were inconclusive and are summarized below:

[3] Key for all pooled meta-analysis and subanalysis tables: R= not reported, NA= not applicable, NS= not stastically significant, RR= risk ratio, WMD= weighted mean difference, [95% CI]
For WMD, a difference <0 favors robotic, *significant heterogeneity

- Shorter operative duration (WMD −22.79 minutes, 95% CI −44.36 to −1.22);
- Shorter length of hospital stay (WMD −0.80 days, 95% CI −1.33 to −0.27);
- Positive margin rate comparisons were inconclusive for pT2 and pT3;
- Reduction in the extent of blood loss (WMD −89.52 mL, 95% CI −157.54 to −21.49);
- Reduced risk of red blood cell transfusion (RR 0.54, 95% CI 0.31 to 0.94); and
- Urinary continence after 12 months, pooled estimates *trended* in favor of RARP (RR 1.08, 95% CI 0.99 to 1.18, NS).

Results of the analysis based on study design and study quality found:

- Three meta-analyses (MA in the text, retrospective studies, and high to good quality studies) showed a significant reduction in operative time for the robotic surgery group. Two of those meta-analyses reported significant heterogeneity between studies.
- Three meta-analyses (MA in the text, retrospective studies, and high to good quality studies) showed a consistent significant reduction for hospital stay favoring the robotic surgery group. Two of those meta-analyses reported significant heterogeneity between studies.
- Five meta-analyses did not show a significant difference for incidence of complications. Three of those meta-analyses reported significant heterogeneity between studies.
- Four out of five meta-analyses (retrospective studies, prospective studies, and high to good quality studies, moderate to low quality) did not show a significant difference for blood loss, and three meta-analyses (retrospective studies, prospective studies, and high to good quality studies, high to good quality) did not show a significant difference for incidence of transfusion.

The operative time, length of hospital stay, positive margin rates, 12 month urinary incontinence, and incidence of complications did not change between the pooled meta-analysis results and the high or good quality studies. The pooled meta-analyses reported significantly decreased incidence of transfusion and estimated blood loss, but both of these findings were not statistically significant in the meta-analyses that included only high and good quality studies.

Table 5. RARP Compared with LRP

Outcome	Pooled MA (Report Text Results)	Retrospective Studies	Prospective Studies	High to Good Quality	Moderate to Low Quality
Operative Time (minutes)	WMD -22.79* [-44.36, -1.22] 9 studies	WMD -34.12* [-67.95, -0.29] 6 studies	WMD -5.87, NS [-39.21, 27.47] 2 studies	WMD -45.47 [-69.97, -20.97] 2 studies	WMD -15.84*, NS [-40.89, 9.21] 7 studies
Hospital Stay (days)	WMD -0.80* [-1.33, -0.27] 7 studies	WMD -0.89* [-1.53, -0.25] 5 studies	WMD -0.20, NS [-0.79, 0.39] 1 study	WMD -1.50 [-1.92, -1.07] 2 studies	WMD -0.47*, NS [-1.11, 0.17] 5 studies
Positive margin rate (all)	RR 0.89, NS [0.66, 1.19] 10 studies	RR 0.89, NS [0.66, 1.19] 10 studies	NA	RR 0.97, NS [0.60, 1.55] 4 studies	RR 0.76, NS [0.47, 1.23] 6 studies
Incidence of complications	RR 0.85*, NS [0.50, 1.44] 9 studies	RR 1.06*, NS [0.55, 2.06] 6 studies	RR 0.54, NS [0.20, 1.45] 2 studies	RR 0.88, NS [0.45, 1.72] 2 studies	RR 0.81*, NS [0.40, 1.67] 7 studies
Blood Loss (mL)	WMD -89.52, * [-157.54, -21.49] 10 studies	WMD -38.97*, NS [-105.80, 27.87] 7 studies	WMD -276.12*, NS [-555.40, 3.16] 2 studies	WMD -153.35*, NS [-314.94, 8.24] 2 studies	WMD -74.95*, NS [-158.05, 8.15] 8 studies
Incidence of transfusion	RR 0.54 [0.31, 0.94] 7 studies	RR 0.54, NS [0.29, 1.01] 4 studies	RR 0.50, NS [0.13, 1.96] 2 studies	RR 0.96, NS [0.27, 3.43] 1 study	RR 0.47 [0.25, 0.87] 6 studies
Urinary incontinence (12 months)	RR 1.08, NS [0.99, 1.18] 2 studies	RR 1.08, NS [0.99, 1.18] 2 studies	NA	RR 1.04, NS [0.95, 1.15] 1 study	RR 1.15, NS [1.00, 1.32] 1 study
Sexual competence	NR	NR	NR	NR	NR

Subsequently Published Study Results

Four additional studies were identified which addressed this key question (Kim 2011a; Kasraeian 2011; Masterson 2011; Tollefson 2011).

An observational, prospective study (Kim 2011a) compared robotic to open radical prostatectomy. The Kim study was rated of poor quality due to significant differences between groups (i.e., age, neoadjuvant hormone therapy use, nerve-sparing surgery frequency, pre-op PSA levels) favoring the RARP group. Patients in both groups had similar time to return of urinary continence (3.7 months robotic vs. 4.3 months open, p=0.161). Additionally, the study reports that men in the robotic group had faster time to potency recovery, as defined by the patient's report of ability to have an erection sufficient for intercourse (9.8 months robotic vs. 24.7 months open, p<0.001). Overall, patients in both groups had similar positive surgical margin rates (27.1% robotic vs. 24.7% open, p=0.487).

An additional retrospective study (Kasraeian 2011), quality rated as good, compared robotic to laparoscopic radical prostatectomy (N=400). The intervention groups at baseline were very

similar statistically, including tumor stage, except for a slightly lower PSA in the robotic group (6.4 vs. 6.8; p<0.001). Operative outcomes reported included:

- Operative time (median) (120 vs. 150 mins; p<0.001);
- EBL (median) (350 vs. 400 mL; p= 0.069); and
- LOS (median) (4 vs. 4 days; p= 0.056).

This study was designed to compare positive surgical margins (PSM) between interventions (13.5% vs. 12%; NS). However, the PSMs were in different locations, posterolateral after robotic surgery (48%; p=0.046) versus at the apex after laparoscopic surgery (53.8%; p=0.038). Median PSM size was smaller in the robotic group (2 mm vs. 3.5 mm; p=0.041).

Another retrospective study (Masterson 2011) quality rated as fair (N=1041) compared robotic to open radical prostatectomy. This study reported no statistically significant differences in PSM location, or biochemical recurrence-free survival at 24 or 60 month follow-ups between groups. The PSM mean length was shorter for the robotic group (3.0 vs. 5.6 mm; p=0.04). The Tollefson (2011) study compared the incidence of surgical site infections between the two intervention groups (0.6% vs. 4.6%; p<0.001). However, rates of other infectious complications (UTI, sepsis/bacteremia did not differ by surgical approach, NS). The baseline characteristics of patients in this study strongly favored the robotic surgery group.

Overall Summary and Limitations of the Evidence

There is moderate strength of evidence to suggest that robotic-assisted radical prostatectomy (RARP), compared to open or laparoscopic approaches, is associated with:

- Shorter hospital stays; and
- Reduced blood loss and transfusion rates.

There is moderate strength of evidence to suggest that robotic-assisted radical prostatectomy (RARP), compared with an open approach, is associated with:

- Increased operative times;
- Reduced positive surgical margin rates (in pT2 patients);
- Increased urinary continence at 12 months; and
- Greater likelihood of sexual function after 12 months.

There is moderate strength of evidence to suggest that robotic-assisted radical prostatectomy (RARP), compared with a laparoscopic approach, had reduced operative times and no difference in positive surgical margin rates in pT2 and pT3 patients. There is low strength of evidence that those undergoing robotic prostatectomy and the open procedure had similar biochemical recurrence-free survival.

The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias. Those in the robotic

intervention arm frequently were younger, had less advanced tumors, and lower PSA baseline scores. In addition, for many of the meta-analyses, there was significant heterogeneity between studies.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Ho [CADTH] (2011) TA Results

Robotic-assisted radical prostatectomy (RARP) compared with open radical prostatectomy (ORP):

The meta-analysis results of the studies pertinent to this comparison favored RARP and are summarized below:

- Lower complication rates (RR 0.73, 95% CI 0.54 to 1.00, NS); and
- Most of the reported complications consisted of urinary leakage, clot retention, bleeding, ileus, wound infection, deep vein thrombosis, pulmonary embolus, urinary tract infection, post-catheter retention, and epididymitis.

Robotic-assisted radical prostatectomy (RARP) compared with laparoscopic radical prostatectomy (LPR):

The meta-analysis results of the studies pertinent to this comparison are summarized below:

- Complication rates in this comparison were found to be similar (RR 0.85, 95% CI 0.50 to 1.44); and
- The most commonly reported complications were urinary leakage, clot retention, bleeding, ileus, wound infection, deep vein thrombosis, pulmonary embolus, urinary tract infection, post-catheter retention, and epididymitis.

Subsequently Published Study Results

A single study (Tollefson 2011) compared the incidence of surgical site infections (SSI) between robotic and open radical prostatectomy groups. This study was quality rated as poor with the baseline characteristics of patients in this study strongly favoring the robotic surgery group. The SSI rates within the initial 30 days post-operatively were increased in the open surgery group (0.6% vs. 4.6%; $p<0.001$). However, rates of other infectious complications (UTI, sepsis/bacteremia) did not differ by surgical approach (NS).

Overall Summary and Limitations of the Evidence

The rate of complications among those undergoing robotic prostatectomy was statistically similar to those undergoing open or laparoscopic prostatectomy. However, the decreased rate of complications in the robotic group trended towards significance when compared to the open group. Similar types of prostatectomy complications were reported in all groups. The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias. Those in the robotic

intervention arm frequently were younger, had less advanced tumors, and lower PSA baseline scores.

There is moderate strength of evidence to suggest that RARP complication rates are statistically similar to those of open radical prostatectomy (ORP) and laparoscopic radical prostatectomy (LRP) procedures.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Ho [CADTH] (2011) TA Results

Most sub-populations above were not reported in Ho [CADTH] (2011). There were 29 studies which reported information regarding the surgeons' expertise. Of these, 11 noted the surgeons were experienced with robotic surgery prior to the study or had chronologically excluded the learning-curve cases (i.e., excluded the first half of a series of cases) from the analysis. Definitions of "experienced surgeons" varied between studies and ranged from 20 to more than 1,000 robotic-assisted surgeries.

<u>Robotic-assisted radical prostatectomy (RARP) compared with open radical prostatectomy (ORP): effect of the learning curve</u>

Similar to the meta-analyses described in KQ #1, meta-analyses were reported in the Ho (CADTH 2011) TA that compared robotic prostatectomy performed only by experienced surgeons to open prostatectomy. The degree of surgeon experience among those performing open procedures was not defined. Definitions of "experienced surgeons" varied between studies and ranged from 20 to more than 1,000 robotic-assisted surgeries. Overall, robotic procedures performed by experienced surgeons were associated with shorter length of stay (WMD -2.04 days, 95% CI -3.18 to -0.89), decreased risk of perioperative complications (RR 0.54, 95% CI: 0.32 to 0.91), decreased risk of positive margins among patients with less advanced tumors (RR 0.58, 95% CI: 0.39 to 0.84), and decreased blood loss (WMD -225.56 mL, 95% CI: -435.46 to -15.67) when compared to open prostatectomy. More advanced tumors (pT3) had similar risk of positive surgical margins between the open and robotic groups even after the learning curve (RR 1.29, 95% CI: 0.83 to 2.02).

In the larger meta-analysis performed in KQ #1, the robotic procedure was associated with longer operative times than the open procedure (WMD 37.74 min, 95% CI 17.13 to 58.34). However, in the sub-group meta-analysis that compared only robotic procedures performed by experienced surgeons to open procedures, there was no significant difference in operative time between groups (WMD 18.00 min, 95% CI: -13.26 to 49.26).

In a comparison of the meta-analyses that included all surgeons to the subgroup meta-analyses that included only experienced surgeons, Ho (CADTH 2011) reported that the experienced robotic surgeons had shorter operative times and length of stay, as well as lower rates of post-operative complication, and positive surgical margins. However, in terms of estimated blood loss, robotic procedures performed by experienced surgeons had more blood loss than those

performed by inexperienced surgeons, but both groups had less blood loss than open procedures. The magnitude of benefit over the open procedure was actually 470mL less blood loss (95% CI: -587.98 to -352.53) among inexperienced surgeons, but only 225 mL less blood loss (95% CI: -435.46 to -15.67) among experienced surgeons.

Subsequently Published Study Results

The Kim (2011a) study briefly reported clinical outcomes among a subgroup of patients who underwent surgery after surgeons were believed to have gained proficiency with the robotic technique (after the first 132 cases). Among the subgroup of patients undergoing surgery by a proficient surgeon, the median time to continence return was 1.6 months in the robotic group, compared to 4.3 months in the open group (statistical significance not reported). When the authors controlled for confounders such as age, PSA, nerve-sparing surgery, etc., the operative method was not a significant predictor of continence recovery.

Overall Summary and Limitations of the Evidence

There is moderate strength of evidence that surgeons experienced in RARP were noted to have improvements in most clinical outcomes (except EBL), when compared to less experienced surgeons:

- Subpopulations in KQ #3, with the exception of surgeon experience, were not reported.
- Surgeons experienced in RARP were noted to have improvements in most clinical outcomes, with the exception of EBL, when compared to less experienced surgeons. These results were studied by analyzing the results of robotic-assisted versus open prostatectomy, and stratifying the robotic group of surgeons by experience.
- A significant limitation of this evidence was the lack of a standardized definition of "experienced surgeon" across the studies.
- The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias. Those in the robotic intervention arm frequently were younger, had less advanced tumors, and had lower PSA baseline scores.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Ho [CADTH] (2011) TA Results

Sixteen individual studies on prostatectomy provided information pertinent to this question; most originated in the United States and were analyzed from the hospital perspective. The majority of these studies did not describe baseline comparative group characteristics (e.g., robotic, open, and laparoscopic). Economic outcomes were reviewed and mean or median total costs of care commonly reported. Among studies, these included: capital equipment (robot) and maintenance contracts, robotic disposables, operating room and supplies, anesthesia, medication, ICU and ward, procedure, outpatient, nursing, medical staff, transfusion, and productivity costs.

Ho [CADTH] (2011) selected the prostatectomy procedure as appropriate for economic evaluation, although the clinical evidence on RARP did not suggest the greatest relative impact on patient outcome. It was, however, the most frequently performed robotic surgical procedure in Canada (62% of all robotic procedures in 2010).

The meta-analyses did not show meaningful differences between RARP and ORP, or RARP and LRP in mortality, general health-related quality of life, or return to normal activities. Differences were seen in urinary function and sexual function at 12 months, both aspects of disease-specific quality of life (QoL). The difference in complication rates between RARP and ORP was statistically significant, only when procedures conducted after the learning curve were considered.

Various instruments, such as Health Surveys (SF-12, SF-36), the Patient-Oriented Prostate Utility Scale (PORPUS), and others, were used to measure utility and QoL in the comparison of RARP and ORP. Overall, the results of comparing these treatment groups were inconclusive and methodologically questionable considering the many potential confounding factors between groups (e.g., differences in baseline pathology and erectile dysfunction, age, use of medications and aids to erectile dysfunction).

Since clinical relevance regarding survival, general QoL, morbidity, and potential disease recurrence could not be shown between groups, a cost-minimization analysis was conducted. For robotic prostatectomy, an economic evaluation is presented as total and incremental costs, per-patient. For RARP compared with ORP, and RARP compared with LRP the following major assumptions were used:

- Males age 61, with prostate cancer; and prostatectomy as recommended therapy;
- Comparators RARP versus ORP and LRP;
- Perspective: publicly funded health care system;
- Clinical effectiveness equivalent between comparators (i.e., cost-minimization);
- Time horizon for patient outcomes = length of hospitalization;
- Robot equipment useful life = 7 years;
- Exchange rate US$1 was CAN$1.016;
- Sensitivity analyses were conducted on the estimated incremental costs of all of the comparators and key model parameters; and
- Base case assumptions: caseload 130 procedures/yr; discount rate 5%.

<u>RARP compared with ORP</u>
The total average costs of RARP were CAN$15,682/patient, and those of ORP were CAN$11,822/patient (incremental costs CAN$3,860). The largest differences were seen in robot costs (CAN$3,785), hospitalization (CAN$3,714), costs of disposables (CAN$2,330), and robot maintenance costs ($1,064).

RARP compared with LRP

The total average costs of RARP were CAN$19,360/patient, and those of LRP were CAN$14,735/patient (incremental costs CAN$4,625). The largest differences were seen in robot costs (CAN$3,785), hospitalization (CAN$1,929), costs of disposables (CAN$1,711), and robot maintenance costs (CAN$1,064).

Note: Hospital costs differed in the two comparisons because two different sets of studies were used to estimate lengths of stay, and their results differed.

Subsequently Published Study Results

No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence

The overall strength of the economic evaluation evidence for the following findings is moderate:

- Comparisons between the various prostatectomy procedure groups (robotic, open, laparoscopic), did not reveal clinically important differences in the major outcomes (mortality, morbidity, QoL, disease recurrence).
- A cost-minimization study found that RARP was more expensive than ORP (incremental cost $3,860 per patient) and LRP (incremental cost $4,625). The incremental costs of RARP might be reduced by increasing caseload, with significant cost reductions seen in the first 200 cases. A benefit of using the robot is a potential saving on hospitalization costs because of reduced lengths of hospital stay. The cost of the robot included in this economic analysis is for the newer model (*da Vinci* Si; US $1.75 million). However, the model reported in most of the literature is the older model (*da Vinci*; US$1.2 million). If this analysis had been carried out using the costs of the earlier model, the increased incremental costs of both comparisons (RARP vs. ORP and RARP vs. LRP), would have been less than what is reported in this cost-minimization study.

Economic analysis is limited by the lack of evidence for significant long-term outcomes (e.g., QoL, return to work, mortality) differences between interventions. This allowed for only a cost-minimization analysis to be performed. The cost-effectiveness for an expensive technology is therefore uncertain and difficult to evaluate due to the paucity of available evidence.

Hysterectomy

There were 34 hysterectomy studies identified comparing robotic surgery with either open or laparoscopic surgery, which addressed the clinical key questions. There were 26 studies identified in the systematic review selected as the sole source of evidence for this procedure, the Ho [CADTH] (2011) TA. Study quality was assessed as being good (five studies), fair to good (16 studies), and poor to fair (five studies). An additional eight studies were identified updating this TA, which were quality rated using a standard CEbP tool. Two studies was quality rated as

good, two as fair, and four as poor. Most of these studies were observational and retrospective in design, and were rated as lower quality on this basis.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Ho [CADTH] (2011) TA Results

These studies involved women with either endometrial or early stage cervical cancer. Both of these cancers are staged according to International Federation of Gynecology and Obstetrics (FIGO) criteria. Many of the meta-analyses performed in this section were associated with high (>50%) I^2 and chi^2 values indicating statistically significant heterogeneity between studies. Relevant potential sources of heterogeneity were investigated for correlation with study outcomes. Subgroup and sensitivity analyses based on study design, study quality, were explored to identify systematic variations. Tables 3 and 4 present the findings of these analyses.

<u>Robotic-assisted radical hysterectomy–robotic-assisted total hysterectomy (RARH-RATH) compared with open radical hysterectomy–open total hysterectomy (ORH-OTH):</u>
The meta-analysis results of the studies pertinent to this comparison are summarized below:

- Longer operative duration (WMD 63.57 minutes, 95% CI 40.91 to 86.22);
- Shorter length of hospital stay (WMD −2.60 days, 95% CI −2.99 to −2.21);
- Reduction of EBL (−222.03 mL, 95% CI −270.84 to −173.22); and
- Reduced risk of transfusion (RR 0.25, 95% CI 0.15 to 0.41).

Results of the analysis based on study design and study quality found:

- Operative time was significantly longer in the robotic surgery group as shown by four of the five meta-analyses (MA in the text, retrospective studies, and high to good quality studies, moderate to low quality). Three of those meta-analyses reported significant heterogeneity between studies.
- Five meta-analyses showed a consistent significant reduction in favor of the robotic surgery group for the following outcomes:
    - Hospital stay;
    - Incidence of complications;
    - Blood loss; and
    - Incidence of transfusion.
- All meta-analyses reported significant heterogeneity except when addressing incidence of complications.

The high or good quality studies and the moderate or low quality studies did not change the conclusions of the pooled meta-analysis.

Table 6. RARH-RATH Compared with ORH-OTH

Outcome	Pooled MA (Report Text Results)	Retrospective Studies	Prospective Studies	High to Good Quality	Moderate to Low Quality
Operative Time (minutes)	WMD 63.57* [40.91, 86.22] 16 studies	WMD 81.57* [39.95, 123.20] 6 studies	WMD 52.75*, NS [-0.86, 106.35] 3 studies	WMD 55.31 [38.50, 72.11] 4 studies	WMD 66.44* [37.14, 95.74] 12 studies
Hospital Stay (days)	WMD -2.60* [-2.99, -2.21] 15 studies	WMD -2.25* [-2.71, -1.80] 6 studies	WMD -3.76* [-5.77, -1.76] 3 studies	WMD -2.69* [-4.22, -1.16] 4 studies	WMD -2.72* [-3.13, -2.30] 12 studies
Incidence of complications	RR 0.38 [0.27, 0.52] 14 studies	RR 0.24 [0.14, 0.43] 5 studies	RR 0.37 [0.21, 0.65] 3 studies	RR 0.60 [0.44, 0.82] 4 studies	RR 0.29 [0.21, 0.41] 10 studies
Blood Loss (mL)	WMD -222.03* [-270.84, -173.22] 14 studies	WMD -202.92* [-290.21, -115.62] 5 studies	WMD -232.53* [-353.44, -111.62] 2 studies	WMD -285.78* [-432.94, -138.62] 4 studies	WMD -210.01* [-265.27, -154.75] 10 studies
Incidence of transfusion	RR 0.25 [0.15, 0.41] 11 studies	RR 0.19 [0.07, 0.51] 4 studies	RR 0.32 [0.15, 0.67] 3 studies	RR 0.23 [0.09, 0.62] 3 studies	RR 0.25 [0.14, 0.45] 8 studies

Robotic-assisted radical hysterectomy–robotic-assisted total hysterectomy (RARH-RATH) compared with laparoscopic radical hysterectomy–laparoscopic total hysterectomy (LRH-LTH):
The meta-analysis results of the studies pertinent to this comparison reported:

- Similar operative times between laparoscopic and robotic groups (WMD 11.64 min, 95% CI: -7.95 to 30.87);
- Shorter length of hospital stay in the robotic group (WMD −0.22 days, 95% CI −0.38 to −0.06);
- Reduction in EBL in the robotic group (−60.96 mL, 95% CI −78.37 to −43.54); and
- Risk of transfusion was decreased in the robotic group, but this difference was not statistically significant (RR 0.62; 95% CI 0.26 to 1.49, NS).

Results of the analysis based on study design and study quality found:

- Four of the five meta-analyses (MA in the text, prospective studies, and high to good quality studies, moderate to low quality) did not show a significant difference for operative time. Three of those meta-analyses reported significant heterogeneity between studies.
- Three meta-analyses (MA in the text, retrospective studies, moderate to low quality studies) showed a consistent significant reduction for hospital stay favoring the robotic

surgery group with the exception of the high or good quality meta-analysis (2 studies) which did not show a difference.

- Reduced incidence of complications in the pooled meta-analysis. However, reductions were not statistically significant in three additional meta-analyses (retrospective studies, prospective studies, high to good quality studies).
- Blood loss: Four meta-analyses consistently showed a significant reduction for EBL in favor of the robotic surgery group.
- Five meta-analyses did not show a statistically significant difference for incidence of transfusion.

Operative time, incidence of transfusion and blood loss outcomes did not change between the pooled meta-analysis results and the high or good quality and moderate or low quality studies.

Table 7. RARH-RATH Compared with LRH-LTH

Outcome	Pooled MA (Report Text Results)	Retrospective Studies	Prospective Studies	High to Good Quality	Moderate to Low Quality
Operative Time	WMD 11.64*, NS [-7.95, 30.87] 13 studies	WMD 28.26* [8.27, 48.26] 7 studies	WMD 27.98, NS [-0.13, 56.09] 1 study	WMD 36.82*, NS [-9.17, 82.80] 2 studies	WMD 6.77*, NS [-13.95, 27.48] 11 studies
Hospital Stay (days)	WMD -0.22* [-0.38, -0.06] 11 studies	WMD -0.27* [-0.44, -0.09] 7 studies	NA	WMD -0.20, NS [-0.86, 0.46] 2 studies	WMD -0.22* [-0.39, -0.05] 9 studies
Incidence of complications	RR 0.54 [0.31, 0.95] 5 studies	RR 0.48, NS [0.14, 1.66] 2 studies	RR 0.89, NS [0.14, 5.88] 1 study	RR 0.80, NS [0.26, 2.44] 1 study	RR 0.48 [0.25, 0.91] 4 studies
Blood Loss (mL)	WMD -60.96 [-78.37, -43.54] 11 studies	WMD -58.77 [-84.23, -33.31] 7 studies	NA	WMD -78.16 [-108.52, -47.80] 2 studies	WMD -55.47 [-77.14, -33.80] 9 studies
Incidence of transfusion	RR 0.62, NS [0.26, 1.49] 5 studies	RR 0.97, NS [0.29, 3.19] 2 studies	RR 0.89, NS [0.25, 3.20] 1 study	RR 1.68, NS [0.41, 6.92] 2 studies	RR 0.42, NS [0.15, 1.15] 3 studies

Subsequently Published Study Results

Five additional studies were identified which addressed this key question. Two studies were assessed as good, two as fair, and one as poor quality with regard to bias.

A multicenter study of 99 consecutive patients (Tinelli 2011) compared treatment for early, FIGO stage I to IIa, cervical cancer between robotic and laparoscopic total hysterectomy and lymphadenectomy. This study was rated as good quality. Comparisons between the robotic and laparoscopic groups noted the following:

- Longer operative time in the robotic group (323 min robotic vs. 255 laparoscopic; p = 0.05)

- No statistically significant differences noted in:
    - Baseline age, BMI, or cancer staging;
    - Mean blood loss, median length of hospital stay, cancer recurrence rate at mean follow-up of 31.1 months; and
    - No conversions from robotic to open were required.

A good quality prospective cohort study of 95 consecutive radical hysterectomy patients (Soliman 2011) compared robotic (RRH, 34 patients), laparoscopic radical hysterectomy (LRH, 31 patients), and open (RAH, 30 patients) approaches. There were no baseline differences in age, BMI, race, cancer stage, or histologic diagnosis. The following outcomes were reported for robotic, laparoscopic, and open surgery, respectively:

- Operative time (mins) (328 vs. 338 vs. 265; p=0.002 for robotic vs. open);
- EBL (mL) (100 vs. 100 vs. 509; p<0.001 for robotic vs. open);
- Risk of transfusion (%) (3 vs. 16 vs. 24; p<0.001 for robotic vs. open); and
- LOS (days) (1 vs. 2 vs. 4; p<0.01 for robotic vs. open).

Soliman (2011) did not report the statistical significance of comparisons between laparoscopic hysterectomy and robotic hysterectomy. Pathologic findings did not differ significantly between groups. The proportion of patients with negative surgical margins was similar between groups (96% robotic vs. 97% laparoscopic vs. 97% open, p=0.99).

A fair quality, retrospective cohort of 90 patients with endometrial cancer evaluated performance of single-port laparoscopy versus robotic and traditional laparoscopic hysterectomy (Escobar 2011). The two treatment arms relevant to this review are the robotic and laparoscopic groups, with 30 patients each. Cohorts were well-matched for age, BMI, comorbidities, and cancer staging. Robotic and laparoscopic groups had no statistically significant differences in terms of operative time (174.0 min robotic vs. 219.5 min laparoscopic, NS), EBL (75 mL robotic vs. 100mL open, NS), and LOS (1.4 days robotic vs. 1.8 days laparoscopic). However, the median number of lymph nodes retrieved during surgery was significantly higher in the robotic group (17.0 nodes robotic vs. 13.0 laparoscopic, p=0.04).

A fair quality prospective cohort study (n=244) comprised of equally sized robotic and laparoscopic groups reported lower EBL in the robotic group (81.1 mL robotic vs. 207.4 mL laparoscopic, p<0.001) (Lim 2011). Additionally, both operative time (147.2 min robotic vs. 186.8 min laparoscopic, p<0.001) and LOS (1.5 days robotic vs. 2.3 days laparoscopic, p<0.001) were shorter in the robotic group. However, the lymph node yield was significantly higher in the laparoscopic group (25.1 robotic vs. 43.1 laparoscopic, p<0.001).

A poor quality retrospective cohort study of 215 patients with endometrial cancer compared pain outcomes in patients undergoing robotic and traditional laparoscopic hysterectomy (Martino 2011). The groups had no difference in age, BMI, cancer stage, or comorbidities. Initial

post-operative pain score (verbally rated by patients on a 1 to 10 scale) was significantly lower in the robotic group (2.1 vs. 3.0, p=0.012). Pain scores were collected at four subsequent points over the next 24 hours and showed no difference between groups. Robotic surgery patients received significantly fewer non-drug pain-relieving interventions from nurses (68.3% vs. 35%, p<0.01), and although there was not a significant difference in the number of pain medication interventions administered, the costs of pain medication were significantly lower in the robotics group ($12.24 vs. $24.45, p<0.01 for the first 24 hours; $3.63 vs. $8.17, p<0.01 for the remainder of stay). This study suffered from high risk of bias due to high potential for selection bias, a risk of confounding as medications were not standardized, a reliance on the patients' verbal pain scale, and questionable clinical significance of a 0.9-point difference in pain scale.

Overall Summary and Limitations of the Evidence

The overall strength of evidence regarding robotic hysterectomy for the following findings is moderate:

- Robotic compared to open hysterectomy was associated with increased operative times, shorter LOS, reduced EBL and risk of transfusion.
- Robotic compared to laparoscopic hysterectomy was also associated with shorter LOS, and reduced EBL, but there were no statistically significant differences in terms of operative duration or risk of transfusion.

The results of the four subsequently published studies did not change the above conclusions. The strength of evidence is low that robotic hysterectomy and laparoscopic hysterectomy were associated with similar cancer recurrence rate at approximately 2.5 years. The strength of evidence is low that robotic hysterectomy was associated with lower pain scores initially, but similar pain score later when compared to laparoscopic hysterectomy.

The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Ho [CADTH] (2011) TA Results

Robotic-assisted radical hysterectomy–robotic-assisted total hysterectomy (RARH-RATH) compared with open radical hysterectomy–open total hysterectomy (ORH-OTH):

The meta-analysis results of the studies pertinent to this comparison favored RARH-RATH and are summarized below:

- Reduced incidence of complications (RR 0.38, 95% CI 0.27 to 0.52); and
- The most commonly reported complications were ileus, wound infection, lymphedema, vaginal cuff hernia, port site hernia, re-operation for bleeding, delayed voiding, deep vein thrombosis, and vaginal cuff dehiscence.

Robotic-assisted radical hysterectomy–robotic-assisted total hysterectomy (RARH-RATH) compared with laparoscopic radical hysterectomy–laparoscopic total hysterectomy (LRH-LTH):
The meta-analysis results of the studies pertinent to this comparison favored RARH-RATH and are summarized below:

- Lower complication rates (RR 0.54, 95% CI 0.31 to 0.95); and
- The most commonly reported complications were wound infection, ileus, lymphedema, vaginal cuff hematoma, bleeding, delayed voiding, deep vein thrombosis, and injury of vena cava.

Subsequently Published Study Results

One good quality study (Soliman 2011) reported differing postoperative infection rates (8.8% vs. 25.8% vs. 53.3%; p<0.001) comparing robotic, laparoscopic, and open surgery, respectively. One fair quality study (Lim 2011) reported lower incidence of conversion to open surgeries in the robotic group than in the laparoscopic group (0.8% vs. 6.5%, p=0.033), as well as lower incidence of major complications (4% vs. 12.3%, p=0.033). In that same study, the decrease in intraoperative complications among the robotic group trended toward significance (0.8% robotic vs. 5.7% laparoscopic, p=0.066), while the incidence of minor complications and the incidence of readmission were similar between groups. Intraoperative complications were defined as bowel, bladder, ureteral, nerve or vascular injury at the time of surgery. Major postoperative complications included cuff dehiscence, cuff cellulitis/pelvic abscess, deep vein thrombosis, pulmonary embolus, myocardial infarction, and bacteremia. Minor postoperative complications included urinary tract infection, wound infection, ileus, and electrolyte abnormalities.

Additionally, the fair quality Escobar study (2011) reported fewer conversions (0 in 30 robotic vs. 1 in 30 laparoscopic) and complications (1 in 30 robotic vs. 2 in 30 laparoscopic) but did not report the statistical significance of these findings.

Overall Summary and Limitations of the Evidence

The overall strength of evidence is moderate that robotic hysterectomy has lower incidence of complications than laparoscopic and open approaches. Further, the strength of evidence is moderate that the types of complications reported are similar among groups.

The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Ho [CADTH] (2011) TA Results

Most sub-populations above were not reported in Ho [CADTH] (2011). Four studies reported information about surgeons' expertise. Information about surgeons' experience was insufficient to perform a sensitivity analysis regarding the impact of the learning curve on clinical outcomes.

Subsequently Published Study Results

Four studies were identified which addressed this key question (Geppert 2011; Lim 2011; Seamon 2009; Subramaniam 2011). Three of the studies involved the subgroup of obese women and the fourth study reported on the learning curve of comparative treatments.

A sub-population study (Geppert 2011) compared robotic and open hysterectomy in morbidly obese women (n=114) for clinical outcomes and was rated as poor quality. Surgical indications were low risk endometrial cancer, bleeding disorders, adenomyosis and myomas. Baseline age was older and the BMI was higher in the robotic versus the open surgery groups (mean age: 52.5 yrs; range 35-85; $p<0.05$); (median BMI 32.5kg/m^2; $p=0.04$). Hysterectomy in obese women has been associated with higher complication rates and presents difficulties with management by conventional laparoscopic techniques. Therefore, the open procedure is the more clinically relevant comparator for this subgroup. In Geppert's (2011) overall analysis, obese patients undergoing the robotic procedure had longer operative times (136 min robotic vs. 110 min open, $p=0.0004$), but less blood loss (100 mL robotic vs. 300 mL open, $p<0.0001$) and shorter mean postoperative hospital stays (1.6 days robotic vs. 3.8 days open, $p<0.0001$). These groups were further stratified by degree of obesity. Among those with a BMI from 30.0 to 34.9, robotic surgery was associated with longer operative times (136 min robotic vs. 108 min open, $p=0.007$), less blood loss (100 mL robotic vs. 300 mL open, $p=0.0002$), and shorter mean postoperative hospital stays (1.6 days robotic vs. 3.3 days open, $p<0.0001$). Among those with a BMI greater than 35.0, the robotic procedure was again associated with decreased blood loss (50 mL robotic vs. 300 mL open, $p=0.0007$) and shorter post-operative hospital stay (1.6 days robotic vs. 5.7 days open, $p=0.0001$), but statistically similar operative time (136 min robotic vs. 128 min open, $p=0.31$) when compared to the open procedure.

Additionally, the Geppert study (2011) compared the first 25 robotic cases to the last 25 robotic cases to evaluate the effect of surgeon experience on surgical outcomes. Patients in the early robotic group were found to have significantly longer operation times (208 min early vs. 136 min late, $p<0.0001$), longer operation room times (290 min early vs. 234 min late, $p=0.002$), greater EBL (200 mL early vs. 100 mL late, $p=0.02$), and longer hospital stays (2.3 days early vs. 1.6 days late, $p=0.008$). When the early and late robotic groups were stratified by degree of obesity, more obese women (BMI ≥ 35.0) retained these learning-curve advantages, with shorter operative times (189 min early vs. 136 min late, $p=0.003$), less blood loss (200 mL early vs. 50 mL late, $p=0.05$), and shorter hospital stays (2.5 days early vs. 1.6 days late, $p=0.02$). However, among less obese women (BMI 30.0 to 34.9), there were no significant differences in blood loss and LOS between early and late groups. Decreases in operative time with surgeon experience remained significant in the less-obese group (217 min early vs. 136 min late, $p=0.002$).

Among obese women in the Geppert study (2011), complications were reported more often in the open group than in the robotic group (35.9% open vs. 12.0% robotic, $p=0.003$). Complications reported in the open group included one bowel obstruction requiring reoperation, one bladder injury, five postoperative fevers, seven postoperative blood

transfusions, one hematoma of the abdominal wall, two cases of urinary retention, two sub-ileus, two vaginal cuff hematomas, one cerebral stroke, and one readmission due to abdominal pain. Among the robotic group, complications included a trocar hernia requiring reoperation nine months later, postoperative vaginal bleeding (one case requiring a transfusion), one ureter injury, one vaginal cuff dehiscence and one rectocele.

Additionally, a poor quality retrospective cohort study of 177 obese patients with endometrial cancer compared robotic to open hysterectomy (Subramaniam 2011). Robotic surgery patients were significantly younger (57.0 years vs. 61.3 years, p=0.01) and had significantly fewer vaginal deliveries (1.79 vs. 2.63, p=0.007). Surgical outcomes comparing the robotic to the open approach reported:

- Operative time (mins) (246 vs. 138 ; p<0.001);
- EBL (mL) (96 vs. 409; p<0.001);
- LOS (days) (2.7 vs. 5.1; p<0.001);
- Incidence of wound complications (4.1% vs. 20.2%; p=0.002);
- Incidence of non-wound complications (9.6% vs. 29.8%; p=0.001); and
- Mortality at 30-days (0.0% vs. 1.0%; p=1.000).

The types of complications reported in the Subramaniam (2011) study included urinary tract infection and pneumonia in the robotic group, compared to cardiac, pulmonary, and gastrointestinal dysfunction in the open group. Ileus was the most common non-wound complication and occurred in 10 patients who had laparotomy and one patient who underwent the robotic procedure.

A poor quality retrospective cohort study of 300 patients with endometrial cancer compared robotic staging to open laparotomy in obese patients (Seamon 2009). Patients who underwent robotic staging were matched by surgeon and BMI to one or two patients who had undergone open staging in the same time period. The robotic surgery patients were significantly younger (58 years vs. 62 years, p=0.03), were significantly less likely to have had prior surgeries (50.5% vs. 62.6%, p=0.04), and were significantly more likely to have ≥3 comorbidities (42.9% vs. 26.3%, p=0.05). Robotic surgery patients had significantly less blood loss (109mL vs. 394mL, p<0.001), lower risk of transfusion (2% vs. 9%, p=0.046), and significantly longer operative time (228 vs. 143 minutes; p<0.001). There was no significant difference in adequacy of staging, percentage of patients undergoing lymphadenectomy, or total lymph node yield, although robotic patients had a higher yield of left aortic nodes (4.8±3.5, 3.5±3.0, P=0.02).

Seamon (2009) reported that the risk of complications was significantly lower in the robotic group than in the open group (RR 0.29, 95% CI 0.13 to 0.65). Complications reported in the open group included major vessel injury (n=1), gastrointestinal events (n=19), pulmonary events (n=5), cardiac events (n=2), acute renal failure (n=3), and others. Complications in the robotic group included cardiac events (n=1), pulmonary events (n=2), gastrointestinal injury

(n=1), and others. There was one reported death in the laparotomy group and none in the robotic group. In addition to the high degree of baseline differences between patients, the study is also at risk of bias due to the absence of an intention-to-treat analysis: patients scheduled for robotic surgery who were converted to laparotomy (and their corresponding match cases) were dropped from the final analysis. This, along with high potential for selection bias, resulted in the study's poor quality rating.

A case-matched, controlled study (Lim 2011), quality rated as fair, compared treatment of endometrial cancer by total hysterectomy/lymphadenectomy by either a robotic-assisted (RHBPPALND) or laparoscopic (LHBPPALND) approach. The latter series was a historical cohort with epochs separated by 10 years. The study objective was to compare the learning curve for both approaches.

Lim (2011) performed an analysis of the first 122 patients, in chronologic order, who underwent either intervention. The surgeons in both cohorts had all just completed the minimum training to be certified in both procedures. Limited information was reported regarding baseline characteristics of both groups. This study was rated fair quality with bias potentially favoring the robotic group in the more modern era. Certain steps in each procedure (i.e., hysterectomy, vaginal cuff closure, etc.) were specified and regression curves derived to determine when the curves stabilized; this established "proficiency" in that step. These milestones were then compared between intervention groups. The overall chronologic case proficiency number for RHBPPALND and LHBPPALND was the 24th case and 49th case, respectively.

Additionally, Lim (2011) reported that there were significantly better outcomes among more experienced surgeons in terms of EBL with regard to the robotic procedure (93.5 mL early group vs. 78.3 mL late group, p=0.030). Similarly, operative time was significantly shortened among experienced robotic surgeons (178.1 minutes early vs. 140.0 minutes later, p=0.015). Differences in other outcomes were not significant between more and less experienced robotic surgeons. In terms of the laparoscopic procedure, there were no statistically significant gains in reported outcomes among more experienced surgeons when compared to less experienced surgeons.

Overall Summary and Limitations of the Evidence

There is low strength of evidence, based on consistent findings across three studies, that robotic versus open hysterectomy in obese and morbidly obese patients results in increased operative time but reduced EBL, LOS and rates of complications. There is low strength of evidence that complications associated with open surgery may be more severe than those associated with robotic surgery among obese women.

There is low strength of evidence that surgical proficiency is achieved earlier with robotic than laparoscopic total hysterectomy approaches. There is low strength of evidence that surgeon experience can influence robotic hysterectomy outcomes in terms of EBL and operative time, while outcomes after laparoscopic hysterectomy are not significantly different depending on surgeon experience.

The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Ho [CADTH] (2011) TA Results

Eight individual studies on hysterectomy provided information pertinent to this question. Three studies originated in the United States, and most were analyzed from the hospital perspective. The majority of these studies did not describe baseline comparative group characteristics (e.g., robotic, open, and laparoscopic). Economic outcomes were reviewed and mean or median total costs of care were commonly reported. Among studies, these variably included: capital equipment (robot) and maintenance contracts, robotic disposables, operating room and supplies, anesthesia, medication, ICU and ward, procedure, outpatient, nursing, medical staff, transfusion, and productivity costs.

The types of economic studies varied, such that their results could not be combined.

- In a decision-analytic model, the estimated per-patient total hospital costs for robotic, open, and laparoscopic hysterectomy (with robot and maintenance costs included) were $8,770, $7,009, and $6,581, respectively.
- Another study analyzed the cost-consequences of robotic compared with open hysterectomy noting that the higher robotic system costs were offset by the shorter length of stay (LOS) in the robotic cases. Thus, total hospital costs were lower in the robotic group ($9,613 ± 1,089 compared with $11,764 ± $6,790), assuming a five robotic caseload/week.
- In another cost-consequence analysis of robotic compared with laparoscopic hysterectomy, LOS was the same in both groups, thus higher hospital costs incurred in the robotic group were not offset by this factor. This resulted in higher total hospital costs for the robotic group ($5,084 ± $938 compared with $3,615 ± $1,026).
- Another large study, using an administrative database, analyzed 1,661 robotic and 34,527 laparoscopic hysterectomies. Outpatient versus inpatient LOS were compared between the interventions, with robotic group incurring higher total hospital costs in both settings:
    - Inpatients ($9,640 ± $1,640 compared with $6,973 ± $1,167); and
    - Outpatients ($7,920 ± $1,082 compared with $5,949 ± $812).
- Another cost-consequence study reported total hospital costs for the robotic, open, and laparoscopic hysterectomy groups were £2,740, £2,678, and £2,323, respectively.
- Another cost-consequence study reported total mean per-patient costs in the robotic, laparoscopic, and open surgery groups as $50,758, $41,436, and $48,720, respectively. Multivariate linear regression analysis confirmed a statistically significant independent

effect of the method of hysterectomy on total costs. Body mass index was found to be the most important predictor of operative costs, regardless of surgical approach.

- Another study compared robotic and laparopscopic hysterectomy and considered only material and personnel costs. The total average surgical costs in the robotic surgery and laparoscopy groups were €4066.84 and €2150.76, respectively.
- One study comparing robotic, open, and laparoscopic hysterectomy included outcomes other than cost.
    - The total average direct costs (labor, pharmacy, supplies, room and board, depreciation) were:
        - Robotic group ($6,002.10 ± $733.90);
        - Open group ($7,403.80 ± $3,310.60); and
        - Laparoscopy group ($5,564.00 ± $1,297.90).
    - The total average indirect (overhead) costs were:
        - Robotic surgery ($2,209.90 ± $417.70);
        - Open group ($5,539.80 ± 2,589.30); and
        - Laparoscopy group ($2,005.80 ± $249.00).
    - The lost wages and household productivity were:
        - Robotic group $3,495;
        - Open group $4,582; and
        - Laparoscopy group $7,540.

Subsequently Published Study Results

The Martino study (2011) briefly reported on the costs of postoperative pain management between individuals undergoing robotic or laparoscopic hysterectomy. Martino (2011) reported that the costs of pain medication were significantly lower in the robotics group ($12.24 vs. $24.45, $p<0.01$ for the first 24 hours; $3.63 vs. $8.17, $p<0.01$ for the remainder of stay).

Overall Summary and Limitations of the Evidence

The overall strength of the economic evaluation evidence for the following findings is moderate:

- Robotic surgery was generally the most costly, followed by open, then laparoscopic approaches;
    - These costs were influenced primarily by operative times, LOS , and cost of supplies; and
    - Incremental costs are influenced by caseload.

Comparisons between the various hysterectomy surgical approaches (robotic, open, laparoscopic) did not report clinically important differences in the major outcomes (mortality, morbidity, QoL, disease recurrence). The perspective of the analysis is important when considering sensitivity factors. From the point-of-view of the hospital, the study model was most sensitive to the costs of the robotic disposables, LOS, and operative time. From a societal perspective, the same model was most sensitive to the costs of the robotic disposables and the recovery time from robotic surgery.

Very low strength of evidence suggests that postoperative pain management costs were lower in robotic hysterectomy than traditional laparoscopic hysterectomy.

The economic analyses are limited by the lack of evidence for significant long-term outcomes (e.g., QoL, return to work, mortality) and differences between interventions.

Nephrectomy

There were 12 nephrectomy studies identified comparing robotic surgery with either open or laparoscopic surgery for renal tumor excision, which addressed the clinical key questions. There were 10 studies identified in the systematic review selected as the sole source of evidence for this procedure Ho [CADTH] (2011) TA. Study quality was assessed as being good (one study), fair to good (eight studies), and poor to fair (one study). An additional two studies were identified updating this TA which were quality rated using a standard CEbP tool. These two studies was quality rated as good. Most of these studies were observational and retrospective in design, and were rated as lower quality on this basis.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Ho [CADTH] (2011) TA Results

There were 10 nephrectomy studies identified which compared robotic surgery with either laparoscopic or open surgery. The study sample sizes ranged from 22 to 247 with the length of follow-up reported varying from 4 months to 4 years. These ten studies focused on patients with renal cell carcinoma. The “TNM” system is used to describe the disease stage. Among the stages, “T” = the size of the primary tumor and local extent of the disease, “N” = the degree of spread to regional lymph nodes, and “M” = the presence of metastases.

Many of the meta-analyses performed in this section were associated with high (>50%) I^2 and chi^2 values indicating statistically significant heterogeneity between studies. Relevant potential sources of heterogeneity were investigated for correlation with study outcomes. Subgroup and sensitivity analyses based on study design, study quality, were explored to identify systematic variations. Table 8 presents the findings of these analyses.

Robotic-assisted partial nephrectomy (RAPN) compared with laparoscopic partial nephrectomy (LPN):

The meta-analysis results of the studies pertinent to this comparison are summarized below:

- Operative duration similar between interventions (WMD 1.42 minutes, 95% CI -15.8, 18.6, NS);
- Shorter LOS in robotic group (WMD −0.25 days, 95% CI −0.47 days to −0.03 days);
- EBL similar between interventions (−17.44 mL, 95% CI −53.63 to 18.75 mL, NS);
- Risk of transfusion (RR 0.85, 95% CI 0.24 to 3.09, NS); and
- Reduced warm ischemic time (WMD −4.18 minutes, 95% CI −8.17 to −0.18 minutes).

Results of the analysis based on study design and study quality found:

- Inconsistent results reported for operative time across all meta-analyses. Four meta-analyses reported significant heterogeneity between studies.
- Four of the five meta-analyses (MA in the text, retrospective studies, high to good quality studies, moderate to low quality) showed a significant reduction in hospital stay in favor of the robotic surgery group. Three of those meta-analyses reported significant heterogeneity between studies.
- Five meta-analyses did not show a significant difference for incidence of complications.
- Four of the five meta-analyses did not show a significant difference for blood loss although the single high to good quality study did.
- Five meta-analyses did not show a significant difference for incidence of transfusion.

In general, there was consistency across most meta-analyses for the following outcomes: hospital stay, incidence of complications, blood loss, and incidence of transfusion.

Table 8. RAPN Compared with LPN

Outcome	Pooled MA (Report Text Results)	Retrospective Studies	Prospective Studies	High to Good Quality	Moderate to Low Quality
Operative Time (minutes)	WMD 1.42*, NS [-15.78, 18.62] 9 studies	WMD 1.89*, NS [-16.50, 20.29] 7 studies	WMD -3.81*, NS [-74.23, 66.61] 2 studies	WMD 15.00 [5.20, 24.80] 1 study	WMD -0.76*, NS [-25.39, 23.87] 7 studies
Hospital Stay (days)	WMD -0.25* [-0.47, -0.03] 9 studies	WMD -0.25* [-0.50, -0.01] 7 studies	WMD -0.20, NS [-0.60, 0.19] 2 studies	WMD -0.30 [-0.41, -0.19] 1 study	WMD -0.28* [-0.41, -0.19] 7 studies
Incidence of complications	RR 1.24, NS [0.79, 1.93] 6 studies	RR 1.30, NS [0.77, 2.20] 5 studies	RR 0.91, NS [0.09, 8.93] 1 study	RR 0.84, NS [0.38, 1.83] 1 study	RR 1.20, NS [0.68, 2.14] 4 studies
Blood Loss (mL)	WMD -17.44*, NS [-53.63, 18.75] 9 studies	WMD -14.16*, NS [-55.70, 27.38] 7 studies	WMD -29.79, NS [-103.43, 43.84] 2 studies	WMD -41.00 [-70.12, -11.88] 1 study	WMD-18.70*, NS [-75.88, 38.49] 7 studies
Incidence of transfusion	RR 0.85, NS [0.24, 3.09] 4 studies	RR 1.20, NS [0.18, 7.82] 2 studies	RR 0.53, NS [0.07, 3.88] 2 studies	RR 0.46, NS [0.04, 4.98] 1 study	RR 1.10, NS [0.24, 5.07] 3 studies
Warm ischemic time (minutes)	WMD -4.18* [-8.17, -0.18] 8 studies	WMD -5.26* [-9.24, -1.28] 6 studies	WMD -1.71*, NS [-13.59, 10.17] 2 studies	WMD -10.80 [-14.28, -7.32] 1 study	WMD -2.69*, NS [-6.20, 0.83] 7 studies

Robotic-assisted radical nephrectomy compared with laparoscopic radical nephrectomy

Two small studies (Hemal 2009; Nazemi 2006) compared robotic radical nephrectomy (n=21) to laparoscopic radical nephrectomy (n=27). In both studies, operative times were significantly longer in the robotic group. Nazemi (2006) reported significantly shorter length of stay among the robotic group, but Hemal (2009) found no significant difference between groups. Across both studies, transfusion rates and estimated blood loss were not statistically different between groups.

Robotic-assisted radical nephrectomy compared with open radical nephrectomy

One small study (Nazemi 2006) compared robotic radical nephrectomy (n=6) to open radical nephrectomy (n=18). The Nazemi (2006) study reported longer operative times (345 min robotic vs. 202 min open, p=0.02), shorter length of stay (3 days robotic vs. 5 days open, p=0.03), and less blood loss (125 mL robotic vs. 500 mL open, p=0.01) among the robotic group. Transfusion rates were not statistically significantly different between groups.

Subsequently Published Study Results

A small, good quality retrospective study (Hillyer 2011) compared outcomes of bilateral, *sequential* robotic nephrectomy (RPN) and laparoscopic partial nephrectomy (LPN). These procedures were proposed to be minimally invasive, nephron-sparing techniques for excising bilateral renal tumors. This report included 9 and 17 patients with *bilateral synchronous renal cell carcinoma* in the two intervention groups, respectively.

- There were no statistically significant differences between the two groups at baseline in terms of age, gender, BMI, American Society of Anesthesiologists (ASA) score, and preoperative renal function (p values ranged from 0.2 to 0.72).
- The interval between sequential partial nephrectomy was similar (4.78 and 4.9 months) for the RPN and LPN groups, respectively (p < 0 .43).
- Surgical outcomes favoring the RPN group noted:
    - A tendency toward shorter warm ischemia time (19 vs. 37 minutes; p=0.056); and
    - Significant lessening in the negative clinical renal functional effect, as measured by the percentage of decrease (-14.6% vs. -37.4%; p=0.03) in glomerular filtration rate (GFR) at 1 month post-operative.

Another retrospective study (Pierorazio 2011) of good quality was identified which compared unilateral RPN (n=48) and LPN (n=102). This study analyzed the perioperative outcomes of a single surgeon performing both interventions. Baseline characteristics of patients and tumor pathology were not statistically different, with the exception of age and BMI which slightly favored the laparoscopic group.

- Surgical outcomes favoring the RPN group noted:
    - Mean operative times (min): 152 (108-265) vs. 193 (100-420), p<.001;
    - Warm ischemic time (min): 14 (8-30) vs. 18 (8-65), p<.001; and
    - Mean EBL (mL): 122 (0-500) vs. 245 (50-1700), p=.001.

No statistically significant differences were noted between groups for either transfusion rates or LOS.

Overall Summary and Limitations of the Evidence

There is low strength of evidence that robotic partial nephrectomy, compared to a laparoscopic approach results in:

- Shorter LOS;
- Reduction in warm ischemic time;
- Mixed results for operative times; and
- No significant differences for transfusion risk or EBL.

There is very low strength of evidence that robotic radical nephrectomy, compared to a laparoscopic approach resulted in:

- Longer operative times;
- Mixed results for LOS; and

- No significant differences in blood loss and incidence of transfusion.

There is very low strength of evidence that robotic radical nephrectomy had longer operative time, shorter LOS, less blood loss, and similar transfusion and complication rates when compared to open radical nephrectomy.

The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Ho [CADTH] (2011) TA Results

Robotic-assisted partial nephrectomy (RAPN) compared with laparoscopic partial nephrectomy (LRN):

- Complication rates did not show a difference between treatments (RR 1.24, 95% CI 0.79 to 1.93, NS); and
- The most commonly reported complications were urinary leaks, bleeding, hematoma, and pulmonary emboli.

Robotic-assisted radical nephrectomy compared with laparoscopic radical nephrectomy and open radical nephrectomy:

Two studies compared these groups and found the following:

- Complication rates were found to be similar when comparing these procedures; and
- Types of complications were not specified for this comparison.

Subsequently Published Study Results

No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence

There is very low strength of evidence that robotic partial nephrectomy and laparoscopic partial nephrectomy had similar complication rates. There is very low strength of evidence that robotic radical nephrectomy, laparoscopic radical nephrectomy and open radical nephrectomy had similar complication rates.

The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Ho [CADTH] (2011) TA Results

Most of the sub-populations listed in the key questions above were not reported in Ho [CADTH] (2011). Information about surgeons' experience was insufficient to perform a sensitivity analysis regarding the impact of the learning curve on clinical outcomes for any of the nephrectomy study results.

Subsequently Published Study Results

One study (Pierorazio 2011) reported perioperative results of cases by consecutive cohort groups of 25 patients in order to analyze the effect of the learning curve of a single surgeon. The early and late robotic cohorts showed no statistically different results in operative time, warm ischemic time, or EBL.

Overall Summary and Limitations of the Evidence

There is very low strength of evidence that robotic partial nephrectomy, compared to a laparoscopic partial approach results in no changes in selected surgical outcomes associated with a learning curve. No evidence was identified that addressed radical nephrectomy procedures for this key question.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Ho [CADTH] (2011) TA Results

Three economic studies which compared various groups of robotic, laparoscopic, and open treatment modalities, included radical nephrectomy procedures. Little information was included regarding baseline characteristics, but a selection bias of smaller tumor size and younger age seemed to favor the surgical outcomes for the robotic groups.

One study noted mean total per-patient hospital costs in the robotic surgery and laparoscopic groups were $11,615 and $10,635, respectively. In another study, because of longer operating room times, the robotic surgery group had the highest operating room costs ($10,252, compared with $4,533 for open surgery, and $7,781 for laparoscopy; P = 0.007) and the highest total hospital costs ($35,756 compared with $25,503 for open surgery, and $30,293 for laparoscopy; P = 0.36). A third study reported that patients undergoing robotic, compared with open nephrectomy had shorter LOS (2.85 days compared with 5.58 days) and lower average direct costs ($11,557 compared with $12,359).

Among the nephrectomy studies, robotic surgery was more costly than laparoscopy, with mixed results compared to open surgery. The three studies either did not include robot costs, or it was unclear whether they were included.

Subsequently Published Study Results

No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence

There is low strength of evidence that the direct and indirect costs for nephrectomy are higher than laparoscopic nephrectomy, but with mixed results when compared to open surgery. The limited information regarding patients and interventions make results of this cost information unclear. Economic analysis is limited by the lack of evidence for significant long-term outcomes (e.g., QoL, return to work, mortality) differences between interventions. No evidence was identified that addressed partial nephrectomy for this key question.

Cardiac Surgery

There were nine studies identified comparing robotic-assisted with non-robotic-assisted cardiac surgeries, which addressed the clinical key questions. Eight of these studies were identified in the systematic review, selected as the sole source of evidence for this procedure Ho [CADTH] (2011) TA. One study was assessed as being of good quality, six were of fair to good quality, and one was of poor to fair quality. An additional study was identified updating this TA which was quality rated as good using a standard CEbP tool. Most of these studies were observational and retrospective in design, and were rated as lower quality on this basis.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Ho [CADTH] (2011) TA Results

Studies which compare robotic-assisted with non-robotic-assisted cardiac surgery procedures are limited. The comparators differ among most studies in such a way that it was not possible to perform a meta-analysis; except for LOS outcomes in mitral valve repair. There were eight studies that compared robotic-assisted procedures with non-robotic-assisted procedures, including five for mitral valve repair, one for coronary artery bypass grafting (CABG), and two for septal defect repair.

Surgical outcomes were reported as follows:

- All robotic cardiac procedures required longer operative times;
    - Statistically significant values ranging from P<0.0001 to <0.002 (one study did not report p value);
- All robotic cardiac procedures noted shorter LOS;
    - Four studies were statistically significance ranging from p=0.039 to <0.001.
    - Pooled results for mitral valve repair noted shorter LOS in robotic group (WMD = -2.15 days; 95% CI -3.57 to -0.73).
- Transfusion rates were reported for two of the eight studies. One study addressed robotic atrial septal repair (compared to partial lower sternotomy) and one study

addressed robotic mitral valve repair (compared to sternotomy). Both studies reported statistically similar findings between the robotic and non-robotic groups.

Subsequently Published Study Results

No studies were identified which met inclusion criteria to update the Ho [CADTH] (2011) for this key question regarding either atrial septal repair or CABG.

A good quality study compared robotic versus open mitral valve repair (Suri 2011) and reported early surgical outcomes of 95 "propensity-matched" pairs, prospectively.

- Extensive matching of baseline demographics, cardiac disease and comorbidities provided that the intervention groups were statistically identical.
- Early surgical outcomes reported:
  - Shorter crossclamp times in open group (31 vs. 75 median mins, p<0.001);
  - Shorter bypass times in open group (40 vs. 101 median mins, p<0.001);
  - Longer post-operative ventilation in open group (6.4 vs. 4.0 median hrs; p<0.001);
  - Longer total ICU stay in open group (22.5 vs. 18.5 median hrs, p<0.001); and
  - Longer LOS in open group (5 vs. 3 median days, p<0.001).
- Early postoperative (within 30 days) surgical outcomes were similar for both groups.

Overall Summary and Limitations of the Evidence

The strength of evidence was low that operative times were longer, LOS was shorter, and statistically similar transfusion rates in the robotic group for all cardiac procedures. These studies were limited by small sample sizes and various technical detail differences across interventions. The generalizability of these results is unclear.

KQ2: **For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?**

Ho [CADTH] (2011) TA Results

Findings on complication rates are reported in only four studies with mixed results between robotic-assisted and non–robotic-assisted cardiac procedures. Complications are not specified in detail.

Subsequently Published Study Results

No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence

There is low strength of evidence on adverse events. Complication rates are mixed among intervention groups. Types of adverse events are not specified in detail.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Ho [CADTH] (2011) TA Results

No information regarding cardiac surgery addressed this key question.

Subsequently Published Study Results

The subsequently published study (Suri 2011) which compared open versus robotic mitral valve repair, and reported early surgical outcomes of 95 "propensity-matched" pairs analyzed results between the first and second halves of their robotic series. In comparing early and later time period surgeries, they noted statistically significant improvements (all p-values <0.001) in bypass time, cross-clamp time, post-operative ventilation time, ICU stay, and LOS with surgical experience.

Overall Summary and Limitations of the Evidence

Subpopulations, with the exception of surgeon experience, were not reported. There is low strength of evidence that surgical experience improves robotic mitral valve repair perioperative outcomes compared to open surgery. Evidence which addresses this key question is limited to a single study of one type of the various cardiac surgeries included in this topic. These findings, therefore, cannot be generalized and the overall strength of evidence for all other cardiac surgery outcomes is very low.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Ho [CADTH] (2011) TA Results

Four economic studies were included for robotic cardiac surgery. All of the studies reported similar patient baseline characteristics among comparison groups. Because of the numerous interventions in this category of studies, the economic studies will be reviewed individually.

One study that compared robotic-assisted hybrid coronary artery revascularization (HCR) and off-pump coronary artery bypass (OPCAB) reported the total hospital costs were higher in the robotic group ($33,401 vs. $28,476 per patient).

Another study compared robotic mitral valve repair (MVR) with conventional MVR, in which the authors reported per-patient hospital costs being higher in the robotic MVR group ($18,503 vs. $17,879).

Another study compared outcomes and costs for patients undergoing minimally invasive coronary artery bypass grafting (mini-CABG) and OPCAB reported that a larger proportion of mini-CABG patients reported a high level of satisfaction with the surgery (76.5% vs. 42.9%;

p=0.035), and return to work or normal activities was quicker with this group (44.2 ± 33.1 days vs. 93.0 ± 42.5 days; p=0.016). When the cost of the robot was added to the total average hospital costs in mini-CABG, the costs for the mini-CABG group versus the OPCAB group was $23,398 ± $3,333 and $16,180 ± $2,777 (p=0.001), respectively.

Another study analyzed the cost incurred in patients undergoing atrial septal defect (ASD) closure (robotic vs. sternotomy) and MVR (robotic vs. sternotomy). In the ASD analysis, the mean intraoperative costs for robotic surgery patients and sternotomy patients were $8,457 ± 2,623 and $7,413 ± $2,581, respectively. Higher costs in the robotic surgery group were attributed mainly to higher operating room and supply costs. The mean postoperative costs for robotic surgery patients and sternotomy patients were $3,164 ± $656 and $3,237 ± $876, respectively. Patients in the robotic surgery group had lower mean ICU, laboratory, and room and board costs. The total average costs in the ASD analysis were $11,622 ± $3,231 for robotic surgery patients, and $10,650 ± $2,991 for sternotomy patients. The addition of the cost of the robot increased the total average cost per case in the robotic ASD group by $3,773. The relative costs in the MVR analysis were comparable.

Subsequently Published Study Results

No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence

The overall strength of evidence on robotic-assisted cardiac procedures is low that the robotic compared to open surgery groups incurred higher average patient costs. However, this was a consistent finding across all types of cardiac procedures analyzed. The evidence base for cardiac surgery is limited with small sample sizes and many different types of interventions reported.

Findings: Other Procedures

Four good quality SRs were identified that evaluated procedures not reported in the Ho [CADTH] (2011) TA. These four SRs include procedures in the following anatomic categories:

- Abdominal (Maeso 2010) SR and meta-analysis;
- Esophageal and gastric cancer resection (Clark 2011) SR;
- Gynecological (Reza 2010) SR/MA; and
- Urological (Thavaneswaran 2009) SR.

These four SRs are used as sole sources of evidence for this report for their respective procedures. All of these SRs were updated by a MEDLINE® search, from their search termination dates, through January 2012. Procedures not evaluated by a previous good quality SR underwent a full MEDLINE® search for the past ten years (January 2002 to 2012). Appendix C details the procedures identified, which procedures were described in SRs, and the MEDLINE® search dates by procedure.

Findings for each procedure are hereafter organized alphabetically.

Adjustable Gastric Band

One SR (Maeso 2010) and two subsequently published studies were identified that compared robotic-assisted to laparoscopic gastric banding approaches.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) identified a single small study that retrospectively compared robotic-assisted (n=10) and laparoscopic (n=10) approaches for the treatment of morbid obesity.

- Operative time was noted to be "40 minutes longer" in the robotic group (statistical significance not reported).
- No significant differences were seen with respect to the LOS (no data provided).

Subsequently Published Study Results

A large comparative retrospective study (Edelson 2010) compared a robotic-assisted (n=287) to laparoscopic (n=120) gastric banding approaches. This study was quality rated as poor. No statistically significant differences in baseline patient characteristics were noted between intervention groups in age, preponderance of women, BMI, nor comorbidities. Patients were followed for one year post-procedure.

The results of comparing robotic to laparoscopic banding groups were:

- For patients with a BMI greater than or equal to 50, operating times were shorter in the robotic group (91.3±19.7 min vs. 101.3±23.7 min, p=0.04). The clinical significance of this outcome (10 minute difference) is unknown.
- No statistically significant differences were noted in the following outcomes:
    - Operating time;
    - LOS;
    - Weight loss at one year; and
    - Conversion to open procedure.

Overall Summary and Limitations of the Evidence

There is low strength of evidence that robotic compared to laparoscopic gastric banding resulted in similar LOS, weight loss at one year, and incidence of conversion to open procedure. Additionally, there is inconsistent evidence that operative time was longer in those undergoing robotic surgery compared to laparoscopic, and so the strength of evidence on this outcome is very low. Studies were retrospective and observational only.

KQ2: **For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?**

Systematic Review and Technology Assessment Findings
No significant differences were seen with respect to the number of complications (no data provided) in the Maeso SR (2010).

Subsequently Published Study Results
In Edelson (2010), the complications reported between robotic and laparoscopic banding groups were:

- Postoperative hospitalization (3.8% robotic vs. 4.2% laparoscopic, NS); and
- Reoperation (3.1% robotic vs. 2.5% laparoscopic, NS).

Overall Summary and Limitations of the Evidence
There were no significant differences between the two interventions based on a low overall strength of evidence for all reported safety and adverse event outcomes. Limited evidence addressed this key question. Studies were retrospective and observational only.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
The Maeso SR (2010) did not address this key question.

Subsequently Published Study Results
The study noted in key question #1 above (Edelson 2010) compared robotic and laparoscopic approaches in gastric banding in a subpopulation of morbidly obese patients.

In this population, the results of comparing robotic to laparoscopic banding groups were:

- For patients with a BMI greater than or equal to 50, operating times were shorter in the robotic group (91.3±19.7 min vs. 101.3±23.7 min, p=0.04). This 10-minute difference is likely of doubtful clinical significance.
- No statistically significant differences were noted in the following outcomes:
    - Operating time for other BMI subgroups;
    - LOS;
    - Weight loss at one year; and
    - Conversion to open procedure.

Overall Summary and Limitations of the Evidence
In the sub-group of morbidly obese patients, there is low strength of evidence that robotic versus laparoscopic gastric banding resulted in shorter operative times in patients with BMIs of

50 kg/m^2 or greater. There were no significant differences between groups for LOS, weight loss at one year, and incidence of conversion to open procedure based on low strength of evidence. Overall, no clinically significant differences were apparent between the two interventions. The sole study that addressed this question was retrospective.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) reports that the cost of robotic-assisted surgery was "more than" $3200 greater than that of laparoscopy ($p<0.05$). No data was provided as to what costs this figure represents.

Subsequently Published Study Results

No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence

The overall strength of evidence is very low that robotic-assisted surgery was more expensive than the laparoscopic procedure. However, evidence was limited as the costs included in the estimate were not described.

Adnexectomy

One SR (Reza 2010) was identified that compare robotic-assisted and laparoscopic adnexectomy procedures.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

The Reza SR (2010) identified one study that compared the robotic-assisted procedure with laparoscopic adnexectomy in 176 patients with adnexal masses. This study was assessed as being of poor quality. The only significant difference between the two procedures was in the increased duration of surgery favoring the robotic group (83 mins vs. 71 mins; $p=0.01$); of doubtful clinical significance.

Subsequently Published Study Results

No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence

There is low strength of evidence that robotic-assisted adnexectomy was associated with longer surgical duration, but was similar across other measured outcomes compared to the laparoscopic procedure.

KQ2: **For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?**

Systematic Review and Technology Assessment Findings
The Reza SR (2010) did not address this key question.

Subsequently Published Study Results
No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence
No evidence addresses this key question.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
The Reza SR did not address this key question.

Subsequently Published Study Results
No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence
No evidence addresses this key question.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
The Reza SR (2010) did not address this key question.

Subsequently Published Study Results
No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence
No evidence addresses this key question.

Adrenalectomy

One study was identified that compared robotic and laparoscopic adrenalectomy procedures.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
One poor quality small study addressed this topic (Brunaud 2004), comparing robotic (n=19) and laparoscopic (n=14) surgery. Baseline patient characteristics showed no statistically significant differences between groups in age, BMI, tumor type and size, nor tumor nonfunctional/functional ratio. The follow-up period was six weeks. Operative times, morbidity, pain, quality of sleep and sleep duration, showed no statistically significant differences between groups.

Overall Summary and Limitations of the Evidence
The overall strength of evidence is very low that robotic compared to laparoscopic adrenalectomy had no significant differences for operative times, morbidity, pain, quality of sleep, and sleep duration.

KQ2: **For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?**

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence
No evidence addresses this key question.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence
No evidence addresses this key question.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence
No evidence addresses this key question.

Cholecystectomy

One SR (Maeso 2010) and two subsequently identified studies were identified that compared robotic cholecystectomy and laparoscopic cholecystectomy.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
The Maeso SR (2010) included one RCT and three cohort studies comparing robotic and laparoscopic cholecystectomy (N=511). A meta-analysis was performed and reported longer surgical times in the robotic group (MD 16.96 min, 95% CI 7.95 to 25.96) but shorter LOS (MD -0.73 days, 95% CI -1.43 to -0.03) compared to the laparoscopic group.

Subsequently Published Study Results
Two studies, both rated as poor quality, were included that compared robotic and laparoscopic procedures (N=56). One study (Jayaraman 2009) was retrospective, with baseline characteristics noted as dissimilar and statistical information not reported. There was longer mean operating time in the robotic group (91 mins robotic vs. 48 mins laparoscopic, $p<0.001$). No other clinically significant outcomes were reported.

Another study (Wren 2011) compared robotic to laparoscopic (historical cohort) cholecystectomy groups. Baseline characteristics showed no statistically significant differences in age, predominance of females, nor BMI. Presence of pre-operative inflammatory disease was different between groups without statistical significance reported. Operative times between groups reported no statistically significant differences.

Overall Summary and Limitations of the Evidence
The overall strength of evidence is low that robotic cholecystectomy was associated with longer operative times, and reduced LOS when compared to the laparoscopic procedure. The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
Maeso (2010) performed a meta-analysis using data from the four identified studies. The meta-analysis suggested that the robotic group had increased odds of complications compared to the

laparoscopic group, but this difference was not significant (OR 2.15, 95% CI 0.64 to 7.25). The nature of the reported complications was not specified.

Subsequently Published Study Results

No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence

The overall strength of evidence is low that robotic cholecystectomy and laparoscopic cholecystectomy had similar complication rates.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) included two studies that reported on learning curve findings. However, the two studies reported mixed results. One study showed shorter operative times in the second half of their series whereas another study showed no such effect of the chronologic case number.

Subsequently Published Study Results

One of the studies (Jayaraman 2009) discussed staffing requirements for robotic surgery. Jayaraman (2009) noted a limitation with this modality, in that the presence of a second experienced surgeon at the bedside is needed to exchange the robotic instruments, retract for exposure, and assist with the procedure.

Overall Summary and Limitations of the Evidence

Findings are mixed as to the differential efficacy of robotic-assisted cholecystectomy surgery based on provider experience. As such, the overall strength of evidence on the impact of surgeon experience is very low.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) performed a meta-analysis that reported increased costs for robotic surgery compared to laparoscopic surgery (MD $1,692, 95% CI $1,139 to $2,245). However, the costs were described as “procedure costs” without further definition or description.

Subsequently Published Study Results

No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence

Low strength of evidence suggests that robotic surgery was associated with increased costs when compared to laparoscopic surgery.

Colorectal Surgery (Colorectal Resection, Colectomy, Mesorectal Excision)

One SR (Maeso 2010) and seven subsequently identified studies were identified that compared robotic-assisted colorectal procedures to laparoscopic and open procedures.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) identified seven controlled, nonrandomized studies that compared robotic-assisted and laparoscopic approaches for colorectal resection in the treatment of benign and malignant disease (N=532). All of the studies were rated as good quality. Sample sizes ranged from 12 to 211, with follow-up times not specified for individual studies. Interventions varied as to what portions of the colon were removed, from the right colon to mesorectal resections for treatment of rectal cancer. The underlying diseases also differed and ranged from diverticular disease and polyps, to adenocarcinoma.

The Maeso SR performed a meta-analysis, which found that robotic surgery had significantly longer surgical times (MD: 39.42 mins, 95% CI 14.99, 63.84) but shorter LOS (MD: -0.26 days, 95% CI -1.55, -1.02).

Other differences between robotic and laparoscopic procedures were reported, but these differences were not statistically significant:

- Reduced blood loss among the robotic group (MD 7.04mL, 95% CI -22.73 to 8.66);
- Earlier bowel function recovery among the robotic group (MD: 0.11 days, 95% CI -0.46 to 0.23); and
- Reduced time to resume oral diet among the robotic group (MD -0.26 days, 95% CI -0.74 to 0.22).

Subsequently Published Study Results

Seven studies were subsequently identified which addressed this topic. One study was a RCT and the remainders were retrospective and observational in design. All of these studies were quality rated as poor.

The RCT study (Patriti 2009) of mesorectal dissection for rectal adenocarcinoma was abandoned after the advantage of robotic surgery was noted, introducing selection bias. Statistically significant differences at baseline were noted as the robotic group had more prior surgery (18/29 vs. 11/37, $p<0.01$) and less distance of tumor from the anal verge (5.9 ± 4.2 cm vs. 11.0 ± 4.5 cm, $p<0.01$). Outcomes were statistically similar between groups in terms of operating time, blood loss, and LOS.

The study by Park (2011a) compared robotic, laparoscopic and open total mesorectal excision for rectal cancer (n=263). Baseline characteristics were similar among groups, except that the robotic group tended to have tumors that were extraperitoneal vs. intraperitoneal in location (p=0.077). Tumors were all of similar stage and proximity to the anal verge. No follow-up period was reported. Park (2011a) reported that the laparoscopic group had significantly shorter operating times than the robotic and open groups (232.6 ± 52.4 mins robotic; 158.1 ± 49.2 mins laparoscopic; 233.8 ± 59.2 mins open; p<0.001). The study also reports that the laparoscopic procedure had significantly shorter LOS than the open procedure, but does not indicate whether the difference between the robotic and open groups was statistically significant (10.4 ± 4.7 days robotic; 9.8 ± 3.8 days laparoscopic; 12.8 ± 7.1 days open; p<0.001). No cases converted to open surgery.

A study by Baek (2010) was case-matched (matching based on gender, age, BMI, and type of procedure) comparing robotic and laparoscopic mesorectal excision for rectal cancer (n=82). Differences at baseline were noted in both prior abdominal surgery (24.4% vs. 43.9%, p=0.06) and previous chemo/radiation therapy (80.5% vs. 43.9%, p=0.001) between respective groups. Surgical outcomes were not statistically different between groups for operative times, blood loss, LOS, or conversions to open surgery.

Another small study (Bianchi 2010) compared robotic to laparoscopic mesorectal excision for rectal cancer (n=50) and followed patients for 10 months. Assignment to treatment groups was based on the availability of the robot. No significant differences were noted between groups at baseline for age, gender distribution, or prior chemo/radiation therapy. The robotic group had lower baseline mean BMI (24.6 kg/m^2 vs. 26.5 kg/m^2, p=0.06). Surgical outcomes were not statistically different between groups for operative times, LOS, ileostomy required, or conversions to open surgery.

An additional study by Park (2010b) compared robotic to laparoscopic mesorectal excision for rectal cancer (N=123) with no follow-up period reported. Baseline matching between groups showed no significant differences in age, BMI, previous chemo/radiation therapy, previous abdominal surgery, or tumor stage. Surgical outcomes noted shorter operative times in the laparoscopic group (231.9 ± 61.4 mins vs. 168.6 ± 49.3 mins, p<0.001), but no statistically significant differences between groups in LOS, or conversions to open procedures.

The study by de Souza (2010) compared robotic and laparoscopic hemicolectomy for treatment of cancer or Crohn's disease (N=175). Significant differences favoring the robotic groups were noted in baseline disease status. No follow-up period was reported. Significant differences favoring the robotic group were noted in operative times (mins) (158.9 ± 36.7 vs. 118.1 ± 381, p<0.001). No significant differences between treatment groups were noted in LOS, EBL, or in conversions to open procedures.

Overall Summary and Limitations of the Evidence

There is moderate strength of evidence that robotic surgery was associated with lower EBL, shorter LOS, similar time to bowel function recovery, and similar time to oral diet when

compared to laparoscopic procedures. The preponderance of evidence suggests that robotic surgery was associated with longer operative times than open or laparoscopic procedures, but the mixed findings reported result in an overall low strength of evidence. There was significant heterogeneity across these studies in terms of baseline differences between groups, and the indications for intervention. Additionally, the observational design of most studies increases the risk of selection bias in favor of the robotic group.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) performed a meta-analysis using data from the identified studies, and reported that the odds of complications between the robotic and laparoscopic groups were not statistically significantly different (OR 0.99, 95% CI 0.59 to 1.65). The specific complications were not reported.

Subsequently Published Study Results

The subsequent studies reported no statistically significantly differences in complication rates between robotic and laparoscopic groups. Most studies reported only aggregate rates without detailing specific complications.

Overall Summary and Limitations of the Evidence

The overall strength of evidence is low that robotic surgery compared to laparoscopic surgery was not significantly different in complication rates.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) identified two studies that reported information regarding learning curve findings. One study reported that surgery time was reduced from “more than 300 minutes to 200 minutes” after their initial 17 robotic-assisted surgery patients. Another study noted “significant differences”, details not specified, in surgery times between the first and last 25 cases in their series.

Subsequently Published Study Results

One of the studies (Park 2010a) reported a post-hoc analysis of the robotic learning curve as reflected in the procedure operative time. This outcome decreased continuously with mean operating time reaching a plateau after 30 cases. In another study by Park (2010b), the changes in operating time for robotic resection in low rectal cancer was observed after 22 of 41 patients had undergone the procedure.

In the discussion section in one study (de Souza 2010) the authors commented on the relative increased technical challenges with rectal resections compared to right hemicolectomy

procedures, in either robotic or laparoscopic surgeries. They suggested, therefore, that it would be more appropriate to attempt a robotic-assisted rectal resection in the latter half of the learning curve, after gaining sufficient experience with robotic assistance in less challenging procedures. Furthermore, a right hemicolectomy is a relatively short procedure, can be performed with just two robotic arms, and is easily converted to the laparoscopic or open approach should the need arise. This makes it ideally suited for the colorectal surgeon at the beginning of the learning curve.

Overall Summary and Limitations of the Evidence

There is low strength of evidence that surgeon experience influenced operative time outcomes between laparoscopic and robotic surgery.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) performed a meta-analysis and reported that the laparoscopic group had lower procedure costs than the robotic group (MD $792, 95% CI $42 to $1543). The costs included in "procedure costs" were not further defined.

Subsequently Published Study Results

One study (Baek 2010) reported "total hospital costs" comparing robotic to laparoscopic mesorectal resection as: ($83,915; $62,601) (NS). No detail was provided regarding cost calculations.

In another study (de Souza 2010), the median cost comparisons between the robotic and laparoscopic groups were all higher in the robotic-assisted group for right hemicolectomy:

- Direct costs ($9303 vs. 7449, p=0.004);
- Indirect costs ($6218 vs. 5103, p=0.003); and
- Total costs ($15, 192 vs. $12,361, p=0.003).

Overall Summary and Limitations of the Evidence

The overall strength of evidence is low that higher costs, both direct and indirect, were associated with robotic compared to laparoscopic colon resection procedures. The cost data in these studies was presented without supporting detail and conclusions drawn from these figures are speculative.

Cystectomy

One SR and five subsequently published studies were identified that compared robotic-assisted cystectomy to open or laparoscopic procedures.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

The Thavaneswaran SR (2009) identified four studies that compared radical cystectomy by robotic-assistance to either open surgery (Guru 2007; Sterrett 2007; Wang 2007) or laparoscopy (Abraham 2007). Indications for these interventions were muscle-invasive bladder cancer requiring the removal of the bladder. All were prospective, non-randomized comparative studies. Baseline characteristics were generally well-matched for age, gender, BMI, ASA score, and clinical stage. Sample sizes were less than 100 in each treatment group. Reported outcomes were typically perioperative outcomes, and length of follow-up was not described.

The Thavaneswaran review (2009) did not perform a meta-analysis. Results of the studies identified by Thavaneswaran (2009) reported that operative time in the robotic group was significantly longer than in the open group in one study (606mL robotic vs. 396mL open, $p<0.05$, Sterrett 2007), but statistically similar in the other two (Guru 2007; Wang 2007). One study reported no difference in operative time between robotic cystectomy and laparoscopic cystectomy (Abraham 2007).

The robotic procedure was reported as resulting in significantly less blood loss when compared to both the open procedure (Sterrett 2007; Wang 2007) and the laparoscopic procedure (Abraham 2007). The third study (Guru 2007) comparing robotic and open procedures did not report on this outcome.

Length of stay among those undergoing the robotic procedure was consistently reported as shorter than those undergoing open surgery (Sterrett 2007; Wang 2007). Compared to laparoscopic surgery, the robotic procedure was not reported as resulting in any significant benefit in terms of LOS (Abraham 2007).

In terms of transfusion rates, the robotic surgery compared favorably to the laparoscopic procedure (42.8% robotic vs. 70% laparoscopic, $p=0.0011$) (Abraham 2007), but was not significantly different from the open procedure in the sole study reporting on this outcome (Sterrett 2007).

The only study comparing laparoscopic cystectomy to robotic cystectomy reported a difference in the incidence of conversion to open surgery, but did not report the statistical significance of this difference (0% robotic vs. 15% laparoscopic, p-value not reported) (Abraham 2007). Two studies comparing robotic cystectomy to open cystectomy reported incidence of conversion to open in the robotic group of 3% (Wang 2007) and 6.3% (Guru 2007).

The incidence of positive surgical margins was higher in the robotic group than in the laparoscopic group in one study, but statistical significance of this difference was not reported

(7.1% robotic vs. 0% laparascopic, p-value not reported) (Abraham 2007). Only one study comparing to open surgery reported on positive surgical margins, which found non-significant differences (Wang 2007).

Subsequently Published Study Results

Five studies were identified all of which compared robotic-assisted cystectomy to open cystectomy for treatment of bladder cancer (Nepple 2011; Ng 2009; Nix 2009; Richards 2010; Sung 2011). Two studies were rated as good quality and three as fair quality. One study was a RCT, the other two were prospective or retrospective cohort studies. Baseline characteristics were well described without significantly different group differences in any of the studies. The results of the most commonly reported outcomes are presently below.

Four of the five identified studies reported significantly longer operative duration among those undergoing robotic cystectomy when compared to those undergoing open cystectomy (410m robotic vs. 345m open; p<0.01 [Nepple 2011]; 4.20h robotic vs. 3.52 open, p<0.01 [Nix 2009]; 530m robotic vs. 420m open, p<0.001 [Richards 2010]; 578m robotic vs. 501m open, p=0.008 [Sung 2011]). Ng (2009) also reported longer operative duration in the robotic group, but the difference was not statistically significant.

Of the four studies reporting EBL as an outcome, all reported significantly less blood loss in the robotic group (460 mL robotic vs. 1172 mL open, p<0.01 [Ng 2009]; 258 mL robotic vs. 575 mL open, p<0.01 [Nix 2009]; 350 mL robotic vs. 1000 mL open, p<0.001 [Richards 2010]; 448 mL robotic vs. 1063 mL open, p<0.001 [Sung 2011]). Two studies reported significantly shorter LOS (5.5 d robotic vs. 8.0 d open, p<0.01 [Ng 2009]; 7 d robotic vs. 8 d open, p=0.014 [Richards 2010]), while three others reported statistically similar LOS between groups (Nepple 2011; Nix 2009; Sung 2011). Of the three studies reporting incidence of transfusion, all identified significantly lower transfusion rates in the robotic group than in the open group (Ng 2009; Richards 2010; Sung 2011).

Positive margins were not significantly different between treatment groups across four of the studies (Nepple 2011; Ng 2009; Nix 2009; Richards 2010), but this was not a reported outcome in fifth study (Sung 2011).

Overall Summary and Limitations of the Evidence

The overall strength of evidence is moderate that robotic surgery compared to open radical cystectomy was associated with decreased blood loss. There is moderate strength of evidence that robotic surgery compared to open radical cystectomy results in increased operative times and decreased LOS. There is very low strength of evidence to show that robotic compared to laparoscopic radical cystectomy is associated with similar operative times, similar LOS, decreased blood loss, and decreased transfusion rate. The study designs were observational and mostly retrospective in nature which can induce selection bias.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Thavaneswaran SR (2009) reported that the incidence of complications was not significantly different between robotic and open groups (Sterrett 2007; Wang 2007) or the robotic and laparoscopic group (Abraham 2007). In general, the complications were not specified in the SR except to mention the most common complication following either surgery procedure was prolonged ileus.

Subsequently Published Study Results

Three of the individual studies (Ng 2009; Nix 2009; Richards 2010) did not detail complications except to indicate that there were no statistically significant differences between the robotic and open treatment groups. The study by Nepple (2011) performed survival analysis of robotic and open cystectomy outcomes and reported them as similar with respect to recurrence-free, disease-specific, and overall survival (all log-rank p values > 0.05). Kaplan-Meier estimates for 2-year outcomes are reported however median patient follow-up was 12.2 months. One study (Sung 2011) analyzed the rates of complication in the robotic and open surgery groups using the Clavien reporting system and noted no significant difference (NS).

Overall Summary and Limitations of the Evidence

There is moderate strength of evidence that there were no significant differences in complication rates between open and robotic surgery. There was very low strength of evidence that complication rates were the same for laparoscopic versus robotic surgery.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

The Thavaneswaran SR (2009) did not address this key question.

Subsequently Published Study Results

No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence

There is no evidence to address this key question.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Thavaneswaran SR (2009) did not address this key question.

Subsequently Published Study Results

One good quality economic review (Lee 2011) included three costs studies which addressed this key question. Comparisons were made between robotic-assisted and open cystectomy using actual and modeled cost data. All studies included two-way sensitivity analyses in order to evaluate the impact of altering both the LOS and operative duration or the case volume. The clinical outcomes which were the largest cost drivers cited were LOS, operative duration, and daily hospitalization costs. The three methods by which urinary diversion is typically achieved have significant cost consequences, particularly due to their associated complications. When patients undergo ileal conduit diversion, then the cost-efficiency of robotic-assisted surgery is most pronounced. In the largest study comparison (n=186), although the overall rate of complications was similar, the cost impact of complications was significantly lower for robotic vs. open cystectomy ileal conduits ($1624 vs. $7202, $p < 0.001$).

All of these cost studies discuss the cost of potential procedure complications, which has not been shown to be different between robotic and open cystectomy. The assumptions are made that lower complication rates would follow with robotic surgery and therefore would have a positive impact on cost savings. This is highly speculative and a significant limitation of this analysis. The various urinary diversion strategies do have different complication rates but that does not directly affect the cystectomy procedure comparison.

Overall Summary and Limitations of the Evidence

This economic review presented a model which indicates that urinary diversion choices can influence costs by changing the incidence of associated complications, which are expensive. This is contrary to the clinical effectiveness evidence which shows that robotic surgery compares well with other techniques in terms of complications. Therefore, the assumptions of this study are speculative, as are their conclusions. The overall strength of evidence for all economic outcomes related to robotic and open cystectomy is low.

Esophagectomy

One SR (Clark 2010) was identified that searched for clinical evidence on robotic esophagectomy. However, the Clark SR (2010) did not identify any comparative studies.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

One good quality SR (Clark 2010) was identified that addressed robotic esophagectomy. The Clark SR (2010) identified nine studies, eight of which reported on unique patients (N=130). Although the SR searched for both comparative and non-comparative studies, the only studies identified were non-comparative case series studies. The Clark SR (2010) does not provide comparative evidence between robotic esophagectomy and other surgical approaches because

none of the eight studies included comparators. Thus, this SR does not provide evidence to help answer this key question. Details of the perioperative outcomes of robotic esophagectomy are available in Appendix D, but are not included here given the lack of comparator group.

Subsequently Published Studies (April 2010 to 2012)
No additional studies were identified.

Overall Summary and Limitations of the Evidence
No evidence was identified to address this key question.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
The Clark SR (2010) does not address the comparative severity or incidence of harms resulting from robotic esophagectomy relative to other surgical approaches. The harms data described in the Clark SR are available in Appendix D, but are not included here because there is not a basis for comparison.

Subsequently Published Studies (April 2010 to 2012)
No additional studies were identified.

Overall Summary and Limitations of the Evidence
No evidence was identified to address this key question.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
No studies were identified.

Overall Summary and Limitations of the Evidence
There is no evidence on differential efficacy or safety across sub-groups for robotic, laparoscopic, or open esophagectomy.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
No studies were identified that addressed this key question.

Overall Summary and Limitations of the Evidence
There is no evidence on the cost or cost-effectiveness of robotic surgery compared to open or endoscopic approaches.

Fallopian tube reanastomosis

One SR (Reza 2010) was identified that compared robotic-assisted fallopian tube reanastomosis to the open procedure.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
Reza (2010) identified two cohort studies that compared robotic fallopian tube reanastomosis to open fallopian tube reanastomosis (Dharia Patel 2008; Rodgers 2007). Both studies were prospective, although Dharia Patel (2008) used retrospective controls. Reza (2010) did not provide specific quality ratings, but did assess the quality of the studies, finding that both had adequate follow-up, clear objectives, and comparable treatment groups.

The Reza SR (2010) performed a meta-analysis, which found that the robotic group had shorter time to return to work (WMD -15.97 days, 95% CI: -19.55 to -12.38), but longer surgical duration (WMD 46.85 min, 95% CI: 34.6 to 59.04) than the open group. The meta-analysis also assessed LOS, pregnancy rate, miscarriage rate, ectopoic pregnancy rate, and EBL, but found no statistically significant differences between groups.

Subsequently Published Studies (October 2009 to 2012)
No additional studies were identified.

Overall Summary and Limitations of the Evidence
Low strength evidence indicates that robotic and open fallopian tube reanastomosis produced similar outcomes in terms of LOS, pregnancy rate, miscarriage rate, ectopic pregnancy rate, intrauterine pregnancy rate, and EBL (Reza 2010). Low strength of evidence suggests that surgical duration was longer with robotic surgery, but women were able to return to work approximately two weeks sooner, on average (Reza 2010). Observational study designs and small sample size limited these findings.

KQ2: **For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?**

Systematic Review and Technology Assessment Findings
Reza reports that the odds of complications were statistically similar between those undergoing robotic tubal reanastomosis and those undergoing open tubal reanastomosis (OR 0.41, 95% CI: 0.08 to 2.06).

Subsequently Published Studies (October 2009 to 2012)
No additional studies were identified.

Overall Summary and Limitations of the Evidence
There is low strength of the evidence that there were no significant differences in complications arising from robotic and open fallopian tube reanastomosis. Observational study designs and small sample size limited these findings.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Subsequently Published Studies (October 2009 to 2012)
None of the subsequently published studies addressed this key question.

Overall Summary and Limitations of the Evidence
There is no evidence on differential efficacy or safety issues across sub-groups for robotic or open tubal reanastomosis.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
Both of the studies (Dharia Patel 2008; Rodgers 2007) identified by the Reza SR (2010) compared costs of robotic tubal reanastomosis to open surgery. In the Rodgers study (2007), robotic surgery was associated with additional costs of $1,446, while Dharia Patel (2008) reported a $2,000 increase in costs for the robotic procedure, plus an additional $300 per newborn. The methods and figures used to calculate these costs were not described.

Individual Study Search Results (January 2002 to 2012)
No additional studies were identified.

Overall Summary and Limitations of the Evidence
There is low strength of evidence that robotic surgery was associated with higher costs than open surgery for tubal reanastomosis. These findings were largely limited by the failure to report how these costs were calculated, but also by the limitations of the underlying evidence presumably used to inform the calculations.

Fundoplication

One SR (Maeso 2010) was identified that compared robotic-assisted fundoplication to open fundoplication.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) identified four RCTs and five controlled, non-randomized studies that compared robotic-assisted and open approaches for fundoplication for the treatment gastroesophageal reflux (N=398). Study quality was noted as lacking for baseline group comparison data in several studies. Sample sizes ranged from 20 to 80, with follow-up times not specified for individual studies. Seven of these reports involved Nissen fundoplication and two involved Dor fundoplication. The Maeso review performed a meta-analysis that found the following non-significant differences between robotic and laparoscopic groups:

- Longer surgery time in the robotic group (20.67 mins, 95% CI -9.69 to 51.02, NS); and
- Reduced LOS in the robotic group (-0.08 days, 95% CI -0.41 to 0.25, NS).

Subsequently Published Study Results

No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence

There is moderate overall strength of evidence that LOS and operative time were similar between robotic and laparoscopic fundoplication.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) performed a meta-analysis, which found non-significant differences in risk of complications between robotic and laparoscopic fundoplication (RD -0.02, 95% CI - 0.12 to 0.08). The types of complications reported were not described.

Subsequently Published Study Results

No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence

There is moderate overall strength of evidence that complications were similar between robotic and laparoscopic fundoplication.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
The Maeso SR (2010) did not address this key question.

Subsequently Published Study Results
No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence
There is no evidence to address this key question.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
The Maeso SR (2010) performed a meta-analysis, which found non-significant differences in costs between the robotic and laparoscopic groups (MD $1596, 95% CI -$181 to $3374). The costs described were "procedure costs," that were not further defined.

Subsequently Published Study Results
No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence
There is low strength of evidence suggesting that laparoscopic procedures had decreased costs compared with robotic fundoplication.

Gastrectomy

One SR (Maeso 2010) and two subsequently published studies were identified that compared robotic-assisted gastrectomy and laparoscopic gastrectomy.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
Maeso (2010) identified two non-randomized controlled studies (N=87) that compared robotic gastrectomy to laparoscopic gastrectomy for the treatment of gastric cancer (Song 2009, Kim 2010). In assessing the quality of these two studies, Maeso notes that there were significant differences in the BMI of patients between groups in the Kim study, while there were differences in the age and year of surgery in the Song study. However, the Maeso SR does not address whether these differences may have favored one treatment over another. The findings of the two identified studies were combined into a meta-analysis in the Maeso SR.

The Clark SR (2010) identified an additional study (n=64) that compared robotic gastrectomy to open gastrectomy (Guzman 2009). This small prospective cohort study was rated as D level evidence by the Clark SR because of its small sample size, observational nature, and failure to perform statistical testing.

The meta-analysis performed in the Maeso SR reports that robotic gastrectomy was associated with significantly shorter LOS (MD -1.38 days, 95% CI -1.84 to -0.93), faster bowel function recovery (MD -0.21 days, 95% CI -0.42 to -0.01), and longer surgical time (MD 37.60 min, 95% CI: 1.28 to 73.92) compared to the laparoscopic procedure. Differences in lymph node yield and EBL were non-significant.

The Clark SR identified only one study, which reported greater mean blood loss (200 mL robotic vs. 353 mL open), longer hospital stays (7 days robotic vs. 10 days open) and shorter operating times (399 min robotic vs. 298 min open) in the open group compared to the robotic group, but that did not perform a statistical analysis.

Subsequently Published Studies (April 2010 to 2012)

The MEDLINE® search identified two additional comparative studies addressing robotic gastrectomy (Woo 2011, Eom 2012). One study was a large retrospective cohort study (n=827) of poor quality because it lacked any follow-up and possessed baseline differences between groups that would favor the robotic group (e.g., the robotic group was younger) (Woo 2011). The other study (Eom 2012) was a small prospective cohort study (n=92) that was also rated as poor quality, primarily because of its small sample size and younger robotic group.

Both Woo (2011) and Eom (2012) reported shorter surgical time in the laparoscopic group compared to the robotic group. While Woo reported less EBL (91.6 ± 152.6 mL robotic vs. 147.9 ± 269 mL laparoscopic, p=0.002, Woo 2011) and shorter LOS (7.7 ± 7.2 days robotic vs. 7 ± 5.7 days, p=0.004, Woo 2011) in the robotic group Eom reported that blood loss and LOS were similar between groups (Eom 2012).

Eom (2012) reported additional outcomes that were statistically similar between groups, including:

- Lymph node yield;
- Lymph node dissection time;
- Time to diet;
- WBC count; and
- C-reactive protein levels (Eom 2012).

Overall Summary and Limitations of the Evidence

The overall strength of evidence for all reported comparators and outcomes was low. Robotic gastrectomy may have some benefits over laparoscopic procedures (e.g., faster time to bowel function recovery) and open procedures (lower EBL). However, surgery time was consistently

longer in robotic procedures compared to laparoscopic or open gastrectomy across all of the identified evidence. Statistically non-significant or mixed findings were reported for other outcomes, including EBL (robotic vs. laparoscopic), LOS, lymph node yield and dissection time, time to diet, white blood cell count, and C-reactive protein levels. These findings are limited by observational study design, potential selection bias from having younger individuals in the robotic treatment arms, and insufficient follow-up..

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

Studies identified within the Maeso SR and Clark SR report briefly on the incidence of complications across surgical modalities. The meta-analysis performed in the Maeso SR reports that there were no significant differences in the incidence of complications. The Clark SR reports a lower incidence of complications in the robotic group, but statistical testing was not performed to determine whether or not this difference was significant. The Clark SR included one study that reported 30 day post-operative mortality (21 robotic and 91 open gastrectomy surgeries). Mortality was high in the robotic group (9.1%) compared with the open group (2.5%).

Subsequently Published Studies (October 2009 to 2012)

The two additional studies identified through the MEDLINE® search similarly reported no significant differences in the incidence of complications.

Overall Summary and Limitations of the Evidence

The strength of the evidence on complications arising from robotic, laparoscopic and open gastrectomy is low. However, the evidence suggests that the incidence of complications was similar between surgical modalities.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

None of the subsequently published studies addressed this key question.

Overall Summary and Limitations of the Evidence

There is no evidence on differential efficacy or safety issues across sub-groups for robotic, laparoscopic, or open gastrectomy.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
Eom (2012) reports that hospital costs were greater for robotic gastrectomy than for laparoscopic gastrectomy ($11,402 vs. $6,071, p<0.001). However, the study does not disclose what was included in these cost estimates.

Overall Summary and Limitations of the Evidence
There is low strength evidence that robotic gastrectomy was associated with higher hospital costs than laparoscopic gastrectomy. These findings are substantially limited in their generalizability, as the methods used to calculate these figures were not described.

Heller Myotomy

One SR (Maeso 2010) included three non-randomized studies which compared robotic and laparoscopic approaches for Heller myotomy to treat esophageal achalsia. The authors of the SR did not report the quality assessment ratings of these studies.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
Maeso (2010) identified three non-randomized controlled studies (N=252) that compared robotic to laparoscopic Heller myotomy for the treatment of esophageal achalasia. In assessing the quality of these studies, Maeso notes that there were significant baseline differences in the weight loss of patients between groups. The SR does not address whether these differences may have favored one treatment over another.

The findings of the three identified studies were combined into a meta-analysis in the Maeso SR. Operative time was found to be not statistically significantly different between groups (MD 38.01, 95% CI -8.79 to 84.81).

Other outcomes were reported in narrative from the individual studies, but statistical analyses were not provided. These included differences in LOS that favored the laparoscopic group, ranging from 0 to 0.72 days, and inconsistent differences in EBL. Additionally, one study reported significant postoperative difference in the pressure exerted by the inferior esophageal sphincter in favor of the robotic group.

Subsequently Published Study Results
No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence
The strength of evidence is low for no significant difference in operative duration between intervention groups. Limitations of these studies include small sample sizes and differences in outcomes reported.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
The meta-analysis performed in Maeso (2010) reported significantly reduced odds of esophageal perforations among those undergoing robotic surgery when compared to those undergoing laparoscopic Heller myotomy (OR 0.11, 95% CI 0.02 to 0.56).

Subsequently Published Study Results
No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence
The strength of evidence is low for reduced incidence of esophageal perforations during robotic compared to laparoscopic procedures.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
The Maeso SR (2010) identified one study (Horgan 2005) that addressed the learning curve for robotic Heller myotomy compared to conventional laparoscopic Heller myotomy. Maeso briefly reported that Horgan (2005) found no statistically significant differences in the learning curve for the robotic procedure compared to the laparoscopic procedure (108 minutes robotic vs. 104 minutes laparoscopic, NS).

Subsequently Published Study Results
No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence
There is low overall strength of evidence that robotic and laparoscopic Heller myotomy procedures have no statistically significant differences in terms of surgeon learning curve.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
The Maeso SR (2010) did not address this key question.

Subsequently Published Study Results
No subsequent studies addressed this key question.

Overall Summary and Limitations of the Evidence
No evidence was identified to address this key question.

Ileovesicostomy

One study was identified that compared robotic and open ileovesicostomy procedures.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
A single, good quality, retrospective study was identified (Vanni 2011) which addresses this key question. In this small (N=15) comparative study, robotic and open ileovesicostomy techniques for the treatment of adult, neurogenic bladder patients, were evaluated for surgical and cost outcomes. The baseline characteristics were well described without statistically significant differences between groups. Surgical outcomes favored the robotic surgery group but were not statistically significant:

- Increased operating time (330 mins (range 240-420) vs. 293 mins (range 240-360), NS);
- Decreased blood loss (100 mL (range 10-250) vs. 257 mL (range 100-800), NS); and
- Shorter LOS (8 days vs. 11 days, NS).

Overall Summary and Limitations of the Evidence
There is limited evidence from a single small study to address this question and the overall strength of evidence is very low that there are no significant differences in operative outcomes.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
No statistically significant difference between intervention groups were noted in this single study (Vanni 2011) regarding continence, chronic UTIs, and complications. No patients in either group developed postoperative hydronephrosis.

Overall Summary and Limitations of the Evidence
There is limited evidence from a single small study to address this question although no significant differences were found. The overall strength of evidence is very low for all reported outcomes.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The (Vanni 2011) study did not address sub-populations.

Overall Summary and Limitations of the Evidence
There is no evidence to address this question.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The single study (Vanni 2011) reported cost outcomes between robotic and open treatment groups:

- Total hospital costs: $17,344 vs. $12,356; (p=0.05); and
- Operating room supplies cost: $3770 vs. $609; (p<0.001).

Costs for OR fees, room and board, anesthesia, and SICU were similar (included direct fixed and variable costs from hospital billing department). Professional fees and robotic maintenance fees ($200,000/year spread across 300 cases), but not purchase price, were included. Post discharge costs were excluded.

Overall Summary and Limitations of the Evidence
Robotic and open ileovesicostomy had similar surgical outcomes in this comparative cohort study. Total inpatient costs were significantly higher in the robotic group, primarily due to the higher operating room supply costs. This single study was limited by both small sample size and observational design and the overall strength of evidence is very low on economic outcomes.

Liver resection

One small, retrospective cohort study (n=32) addressing robotic liver resection for removal of liver tumors was identified.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs were identified that address this key question.

Individual Study Search Results (2002 to 2012)
The MEDLINE® search identified one small, retrospective cohort study (n=32) addressing robotic liver resection for removal of liver tumors (Berber 2010). The study was rated poor quality because of its small sample, selective reporting of findings, and retrospective design. Additionally, two authors disclosed that they were also consultants for the robot manufacturer.

The Berber (2010) study reported that robotic and laparoscopic liver resection yield similar outcomes in terms of operating time, EBL, tumor recurrence, and overall disease-free survival.

Overall Summary and Limitations of the Evidence
Very low strength of evidence suggests that there were no significant differences between surgical modalities for liver resection. However, these findings are limited by the poor quality of the only study that evaluated these outcomes.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs were identified that address this key question.

Individual Study Search Results (2002 to 2012)
Berber (2010) reports that complication incidence was lower in the robotic group than in the laparoscopic group (11% vs. 17%), but did not report whether this difference was statistically significant. Additionally, the incidence of conversion to open was higher in the robotic group, but no statistical tests on the significance of this finding were reported.

Overall Summary and Limitations of the Evidence
The strength of the evidence on complications arising from robotic and laparoscopic liver resection is low. These findings are limited by the absence of statistical comparisons between groups.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (2002 to 2012)
No studies were identified that addressed this key question.

Overall Summary and Limitations of the Evidence
There is no evidence on differential efficacy or safety issues across sub-groups for robotic or laparoscopic liver resection.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (2002 to 2012)
No studies were identified that addressed this key question.

Overall Summary and Limitations of the Evidence
There is no evidence on the relative cost of robotic liver resection compared to laparoscopic liver resection.

Lung surgery

Two studies were identified that compared robotic-assisted lung procedures to open surgery.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs were identified that addressed this key question.

Individual Study Search Results (2002 to 2012)
The MEDLINE® search identified two comparative studies addressing robotic lung surgery. One study was a poor quality retrospective cohort study (n=36) that compared robotic thoracoscopic resection to open sternotomy for the treatment of mediastinal tumors (Balduyck 2010). The Balduyck study was limited by its small sample size, limited patient characteristic descriptions, and differences between treatment groups (e.g., patients receiving open sternotomy had larger masses). The other study was a fair quality retrospective cohort study (n=108) that compared robotic lobectomy to open lobectomy for the treatment of lung cancer (Veronesi 2010). The Veronesi study (2010) used propensity-score matching to match patients in the two treatment groups, and was limited primarily by its retrospective nature.

Compared to open lobectomy, the robotic procedure was associated with shorter LOS ($p=0.002$), but longer operating times ($p<0.001$) and lower lymph node yield ($p=0.04$) (Veronesi 2010).

Compared to open sternotomy, robotic thoracoscopic resection was associated with less pain and higher QoL scores at three months post-op (p-values not reported), but statistically similar operating times and LOS (Balduyck 2010).

Overall Summary and Limitations of the Evidence

The strength of evidence comparing robotic and open median sternotomy is low for all reported outcomes. The robotic procedure may have had benefits over the open procedure, including less post-operative pain and higher QoL scores (Balduyck 2010). Additionally, the strength of evidence comparing robotic lobectomy to the open procedure is low for all outcomes, but suggests that robotic lobectomy was associated with shorter LOS, longer operating times, and lower lymph node yield than in the open surgical group (Veronesi 2010).

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

No SRs or TAs were identified that address this key question.

Subsequently Published Studies (October 2009 to 2012)

Both Veronesi (2010) and Balduyck (2010) reported briefly on the safety and incidence of adverse events in robotic lung surgery as compared to open procedures. Both studies indicate that procedures are similar in terms of complication incidence, including need for transfusion and mortality rate.

Overall Summary and Limitations of the Evidence

The strength of the evidence on complications arising from robotic and open lung surgery is low, but consistently reports that the incidence of complications was similar between surgical modalities.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (2002 to 2012)

The Veronesi study (2010) performed a subanalysis on perioperative outcomes based on the surgeon's experience. Patients undergoing robotic procedures were stratified into those in the early robotic group, mid-robotic group, and late robotic group to assess how the outcomes of robotic surgery varied as the surgeon gained more experience. Veronesi reported that operating time significantly decreased between the early robotic and late robotic groups, but was still significantly longer than the open surgery group. While LOS between the early robotic group and the open group were similar, the late robotic group had significantly shorter hospital stays than the open group.

Overall Summary and Limitations of the Evidence
There is low strength of evidence suggesting that robotic lobectomy had differential efficacy depending on the surgeon's level of experience. These findings are primarily limited by small sample size and observational study design.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Veronesi study (2010) briefly reports that robotic procedures cost € 2000 more than open procedures, but no details were provided on how this estimate was calculated.

An additional cost study (Park 2008) was identified that reported that the total hospital costs of robotic lobectomy were almost $4,000 lower than those of open lobectomy. However, the study was rated as poor quality because it lacked several important methodological features. Specifically, no sensitivity analysis was performed and no assumptions were stated. Additionally, the patient characteristics from the underlying evidence were not described, and the authors stated that most patients undergoing robotic procedures were also undergoing concurrent procedures. However, it was difficult to ascertain whether or not the authors somehow accounted for this in their cost analysis.

Overall Summary and Limitations of the Evidence
There is mixed evidence on the costs of robotic lung surgery relative to open lung surgery. Both of the identified studies possess significant limitations that prohibit conclusions on this key question. The strength of evidence on economic outcomes is low.

Myomectomy

One SR (Reza 2010) and three subsequently published studies were identified that compared robotic, laparoscopic, and open myomectomy procedures.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
Reza (2010) identified three prospective cohort studies (N=189), one of which used historical controls, to compare robotic to laparoscopic, and to open surgery for the treatment of leiomyomata. The good quality Reza review assessed the quality of the studies, noting that they were not randomized or blinded, but had clear objectives and adequate follow-up. A meta-analysis was performed including two studies that compared robotic and laparoscopic

approaches, and reported significantly less EBL in the robotic group (WMD: -72.56mL, 95% CI -133.22 to -11.50) but similar operative times between modalities (WMD: 0.18 min, 95% CI: -54.42 to 54.79).

The remaining study compared robotic to open surgery and reported longer operative time (80 min longer, p<0.001), less EBL (170 mL less, p=0.011), and shorter LOS (2 days shorter, p=0.001) in the robot group.

Subsequently Published Studies (October 2009 to 2012)

The MEDLINE® search identified three additional studies comparing robotic to either laparoscopic and/or open myomectomy for the treatment of leiomyomata (Ascher 2010; Barakat 2011; Nash 2011) that addressed this key question. Ascher (2010) and Barakat (2011) were rated as poor, while Nash (2011) was rated as fair. The surgical outcomes of the Barakat study were incompletely reported, without explanation, and are not presented here; no conclusions could be drawn from these results.

Both Ascher (2010) and Nash (2011) found that the robotic procedure was associated with longer operative times than the open procedure (192.3 m robotic vs. 138.6 m open, p=0.01, Ascher 2010; 226.41 m robotic vs. 114.54 m open, p<0.0001, Nash 2011). While Ascher reported less blood loss in the robotic group (26.3 mL robotic vs. 459 mL open, p=0.009, Ascher 2010), the Nash study found no significant difference between groups (2011). Additionally, both studies reported significantly shorter LOS in the robotic group (0.51 d robotic vs. 3.3 d open, p<0.01, Ascher 2010; 0.70 d robotic vs. 2.3 d open, p=0.001, Nash 2011).

Overall Summary and Limitations of the Evidence

Low strength of evidence indicates that robotic myomectomy was associated with lower blood loss and shorter length of stay, compared to both open and laparoscopic groups, but longer duration of surgery when compared to the open approach. Operative times were similar for robotic compared with laparoscopic approaches. Despite methodological limitations of retrospective design and relatively small samples, these results were consistent across studies.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Reza SR (2010) does not report findings on complications associated with robotic, laparoscopic, or open myomectomy.

Subsequently Published Studies (October 2009 to 2012)

Ascher (2010) reports that operative and postoperative complications were “similar” between the robotic group and the open surgery group. However, the Ascher study also reports significantly decreased incidence of post-operative fever in the robotic group (1.3% vs. 38%;

p<0.001). Nash (2011) also reported no statistically significant difference in proportion of complications between two comparison groups.

Overall Summary and Limitations of the Evidence

The strength of the evidence regarding similar complications arising from robotic, laparoscopic and open myomectomy is low. Although the Ascher study reported similar rates of complications between groups, the study also cited lower febrile morbidity in the robotic group (2010). However, differences in post-operative monitoring may account for this finding, as the robotic group self-reported fever.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Subsequently Published Studies (October 2009 to 2012)

None of the subsequently published studies addressed this key question.

Overall Summary and Limitations of the Evidence

There is no evidence on differential efficacy or safety issues across sub-groups for robotic, laparoscopic, or open myomectomy.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

Two studies were identified that addressed the cost issue (Advincula 2007; Behera 2011). One cost analysis was identified that compared robotic to open myomectomy (Advincula 2007). The operative outcomes reported in this study were included in the Reza SR, but Reza (2010) did not report on Advincula's cost analysis. Overall, the cost-analysis was rated as fair quality and was primarily from a U.S. hospital perspective. Advincula reports that both charges (professional and hospital) and reimbursement associated with robotic surgery were greater than those of open surgery ($36,031 vs. $18,065 and $15,444 vs. $8,857, respectively). However, the difference in reimbursements was not statistically significant. The biggest single difference was in a component of hospital charges, "operating department charges" ($16,916 robotic vs. $2165 open); most other hospital charges were greater for open procedures. Five year depreciation costs accounted for $10,569 of operating room costs for each robotic procedure.

An additional cost minimization study (Behera 2011) was reported for the comparison of robotic, laparoscopic, and open myomectomy. Two scenarios were examined for direct hospital costs only; one with an existing robot and the other requiring the purchase of the robot.

Robotic vs. laparoscopic vs. open surgery (direct costs)
Existing robot model ($7280; $6199; $4937)

- Open procedure remained the least expensive after sensitivity analysis, unless:
    - Length of hospital stay for open surgery was greater than 4.3 days (laparoscopic became least expensive); or
    - Surgeon's fee for open surgery was greater than $3473 (laparoscopic became least expensive followed by robotic).
    - Cost of robotic procedure consistently higher than laparoscopic
        - Robotic only less expensive if disposable instrument costs were less than $1400 and laparoscopic disposable costs remained $1151

Robot purchase model

- Robotic cost increased incrementally by $2814, $1939, and $1090 when purchase of robot was amortized over 12, 18 and 32 months, respectively

Overall Summary and Limitations of the Evidence

There is low strength of evidence that robotic myomectomy was associated with higher total hospital costs than both laparoscopic and open myomectomy. However, these findings are limited by the clinical evidence that informed this economic analysis. In particular, the underlying clinical outcomes were obtained by a retrospective study that did not perform any follow-up of patients, which may greatly affect estimates of costs associated with complications.

Oropharyngeal Surgery

One study was identified that compared robotic-assisted oropharyngeal surgery to open surgery.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

One retrospective cohort study (Dean 2010) compared robotic (n=7) and open (n=14) salvage surgical resesections for recurrent oropharyngeal neoplasms. This study was rated as poor quality as the comparison groups were from different epochs and baseline group differences were not statistically analyzed. Many outcomes were presented in narrative fashion. Follow-up time was six months.

Overall, the Dean study identified no significant differences in outcomes between robotic and open groups. Although LOS was shorter (5.0 d robotic vs. 8.2 d open, NS) and dependence on a gastrostomy tube was less prevalent in the robotic group (0% robotic vs. 43% open, NS), these findings were not statistically significant.

Overall Summary and Limitations of the Evidence

The strength of evidence is very low that robotic oropharyngeal salvage surgery for recurrent neoplasm was was not significantly different for LOS and gastrostomy tube dependence at six months compared to open surgery.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

This single study reported no complications in the robotic salvage group. Two patients in the open resection group developed post-operative wound infections and two developed hematomas. However, all patients in both groups underwent either concomitant or staged neck dissections. The study report appeared to present these complications as due to the neck dissection surgery though occurring in the open surgery group.

Overall Summary and Limitations of the Evidence

There is very low strength of evidence regarding complications of robotic compared with open oropharyngeal surgery.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence

No studies addressed this key question.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
No studies addressed this key question.

Overall Summary and Limitations of the Evidence
No studies addressed this key question.

Pancreatectomy

Four studies were identified that compare robotic, open, or laparoscopic approaches to pancreatectomy.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
Four retrospective cohort studies (Kang 2010b; Kang 2011a; Waters 2010; Zhou 2011) compared robotic, open, or laparoscopic approaches to pancreatectomy. All were rated as poor quality. Baseline group differences were noted in age, tumor type, tumor excision site (central or distal pancreas, or pancreatoduodenectomy), presence of symptomatology, and specimen length. Sample sizes varied from 15 to 57 (N=133). Follow-up times ranged from none to 19 months. Surgical outcomes will be reported by grouping comparative interventions.

The robotic procedure was found to have favorable outcomes compared to the laparoscopic procedure in terms of blood loss (275.0 ± 221.7 mL robotic vs. 858.3 ± 490 mL laparoscopic, p=0.038, Kang 2011b) in one study, but non-significant differences in two other studies (Waters 2010, Kang 2011b). Compared to the open procedure, the robotic procedure had significantly less blood loss in two studies (153.75 ± 43.4mL robotic vs. 210 ± 53.2 mL open, p=0.045, Zhou 2011; 275.0 ± 221.7 mL robotic vs. 858.3 ± 490 mL open, p=0.038, Kang 2011b). The same two studies also reported shorter length of stay among those in the robotic group compared to those in the open group (16.4 ± 7.1 days vs. 24.3 ± 7.1 days, p=0.04, Zhou 2011), though the difference reported in the Kang (2010b) study was not significant. Robotic surgery and laparoscopic surgery were found to have similar LOS in one study (Kang 2011b).

Overall, operative times in the robotic groups were consistently longer than those of the laparoscopic groups (Kang 2011a; Waters 2010) or open groups (Kang 2011b; Waters 2010; Zhou 2011).

Overall Summary and Limitations of the Evidence

There is low strength of evidence that robotic pancreatectomy was associated with longer operative times compared to laparoscopic and open surgical approaches. The strength of evidence is very low that LOS and EBL decreased for robotic versus open procedures. There is very low strength of evidence of mixed results for blood loss, but similar LOS, compared to laparoscopic procedures.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

The four studies above addressed this key question in aggregate only. Only one of four studies noted a significant difference between groups in overall complications (Zhou 2011) favoring the robotic group (25% robotic vs. 75% open, p=0.04). The other two studies comparing open and robotic pancreatectomy found no significant differences in complications between groups (Kang 2011b; Waters 2010). Both studies comparing laparoscopic and robotic pancreatectomy found no significant differences (Kang 2011a; Waters 2010).

Overall Summary and Limitations of the Evidence

There is low strength of evidence that robotic surgery resulted in mixed findings for complications compared to open and laparoscopic approaches.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

No studies were identified which addressed this key question.

Overall Summary and Limitations of the Evidence

No studies addressed this key question.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
One study (Waters 2010) provided a fair quality cost analysis from the U.S. hospital perspective, reporting direct, variable costs, and excluding professional fees. Data was collected from hospital accounting records and included operative time and supplies, anesthesia, nursing, laboratory, and overall hospital stay costs. Adjusted operative costs included amortized cost of robotic system. Post discharge and other follow-up care costs were excluded from the analysis.

Cost outcomes were as follows comparing robotic vs. laparoscopic vs. open surgery:

- Operative, unadjusted: $4898; $3072; $3510, global p=0.04;
- Operative, adjusted: $6214; N/A; N/A;
- Hospital stay: $5690; $9828; $12,011, global p=0.01;
- Total, unadjusted: $10,588; $12,900; $15,521, NS; and
- Total, adjusted: N/A; N/A; $11,904, NS for comparison of adjusted robotic with other unadjusted costs.

Overall Summary and Limitations of the Evidence
There is an overall low strength of evidence that robotic, open and laparoscopic pancreatectomy had similar costs after adjustment for amortized equipment costs.

Pyeloplasty

One SR (Thavaneswaran 2009) and one subsequently published study were identified that compare robotic and laparoscopic pyeloplasty.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
Thavaneswaran (2009) identified four non-randomized comparative studies (N=224) that compare robotic pyeloplasty to laparoscopic pyeloplasty for the treatment of ureteropelvic junction obstruction (Bernie 2005; Link 2006; Weise 2006; Yanke 2008). Thavaneswaran notes that methodological quality of the studies was assessed, but does not assign formal quality ratings for each study.

A meta-analysis of the studies identified in the Thavaneswaran review was not performed. Individual study findings suggested that those undergoing laparoscopic pyeloplasty may have shorter operating times than those undergoing robotic surgery (100.2 m vs. 80.7 m, Link 2006).

However, two other studies identified by Thavaneswaran (2009) reported that the operating time between groups was statistically similar (Bernie 2005; Weise 2006).

Several statistically non-significant findings were reported. Among these were non-significant differences in:

- EBL (Bernie 2005; Link 2006; Weise 2006);
- LOS (Bernie 2005; Link 2006; Weise 2006);
- Surgical success rate (Link 2006; Weise 2006; Yanke 2008);
- Post-operative pain (Weise 2006); and
- Renal function (Bernie 2005).

Subsequently Published Studies (February 2009 to 2012)

The MEDLINE® search identified one additional retrospective cohort study (Bird 2011), which was quality-rated as poor for its retrospective design and borderline high loss to follow-up (21% lost). Additionally, the robotic group was more likely to have secondary ureteropelvic junction obstruction. However, any resulting bias would likely have favored the laparoscopic group.

The Bird study (2011) found non-significant differences between robotic and laparoscopic groups in terms of EBL, LOS, and operative time.

Overall Summary and Limitations of the Evidence

Low strength evidence found that robotic pyeloplasty and laparoscopic pyeloplasty achieve similar outcomes in terms of EBL, LOS, surgical success rate, post-operative pain, and renal function. Mixed evidence suggests that laparoscopic surgery may have yielded shorter operating times than robotic procedures. Although the strength of the evidence is low, there is notable consistency across most findings.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The Thavaneswaran SR (2009) describes the complications reported in the four identified studies regarding robotic pyeloplasty. Overall, the incidence of complications is not significantly different between robotic and laparoscopic surgical modalities across all four studies.

Subsequently Published Studies (October 2009 to 2012)

Bird (2011) reports that the incidence of complications did not differ between robotic and laparoscopic surgical groups.

Overall Summary and Limitations of the Evidence
The strength of the evidence on complications arising from robotic and laparoscopic pyelplasty procedures is low, but consistently reports that the two surgical approaches were similar in this regard.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Subsequently Published Studies (October 2009 to 2012)
None of the subsequently published studies addressed this key question.

Overall Summary and Limitations of the Evidence
There is no evidence on differential efficacy or safety issues across sub-groups for robotic or laparoscopic pyeloplasty.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
One study was identified that addressed the cost of robotic pyeloplasty compared with laparoscopic pyeloplasty (Link 2006). Although this study was included for its clinical outcomes data in the Thavaneswaran SR, cost data was not included. The good quality Link (2006) analysis used modeling to estimate to the projected perioperative costs of the two procedures, and assessed its findings using a one-way sensitivity analysis. Link reported that laparoscopic pyeloplasty operating time would need to increase 6.5 hours for robotic pyeloplasty to reach cost equivalence. Overall, Link reports that the robotic procedure is at least 1.7 times more costly than the laparoscopic procedure.

Overall Summary and Limitations of the Evidence
There is low strength of evidence indicating that the cost of robotic pyeloplasty was greater than laparoscopic pyeloplasty based on projected perioperative costs from a single good quality study. These findings are limited by potential bias that may have been introduced if the robotic procedures were the first ones performed by surgeons at the institution.

Rectopexy

One SR (Maeso 2010) and two subsequently published studies were identified that compared robotic rectopexty to open or laparoscopic rectopexy procedures.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

One good quality SR (Maeso 2010) was identified that addressed robotic rectopexy for the treatment of rectal prolapse. Maeso identified one small (n=33) non-randomized controlled study (Heemskerk 2007). The Maeso SR does not assign Heemskerk an individual quality rating, but did assess the quality of the study, noting that it was not blinded or randomized, and that there were significant differences between groups in terms of age. However, the effect that this difference may have had on the results was not addressed.

The Maeso SR reported that Heemskerk study found longer surgical times in the robotic group (39 minutes longer) but did not test the significance of this difference. Additionally, 5% of patients in the robotic group were converted to open surgery, while no laparoscopic patients were converted (Heemskerk 2007). Several outcomes were reported as being the same between groups, including LOS, time to defecation, postoperative constipation, and postoperative incontinence (Heemskerk 2007).

Subsequently Published Studies (August 2009 to 2012)

Two additional comparative studies were identified. One was a poor quality retrospective cohort study (n=63) that compared robotic rectopexy to laparoscopic rectopexy (Wong 2011). The other was a poor quality retrospective cohort study (n=82) that compared robotic rectopexy to both laparoscopic rectopexy and open rectopexy (de Hoog 2009). Both studies were limited by small sample size and retrospective study design.

Robotic rectopexy was reported as having longer operating times when compared to both the laparoscopic procedure (221 ± 39m robotic vs. 162 ± 60m laparoscopic, p=0.0001, Wong 2011) and open procedure (154 ± 47m robotic vs. 119 ± 31m laparoscopic, p≤0.02, de Hoog 2009). Additionally, those in the robotic group had greater odds of disease recurrence than those in the open group (OR=24.41, 95% CI: 1.45-410.7, de Hoog 2009).

However, Wong (2011) reported that the robotic procedure was associated with less blood loss than the laparoscopic procedure (6 ± 23mL robotic vs. 45 ± 91mL laparoscopic, p=0.048). Additionally, those undergoing robotic rectopexy had shorter LOS than those undergoing the open procedure (2.6 d robotic vs. 3.5 d open, p<0.001, de Hoog 2009).

Overall Summary and Limitations of the Evidence

Low strength evidence suggests that robotic rectopexy was associated with longer operating times and higher odds of recurrence of rectal prolapse compared to open or laparoscopic procedures. These findings are limited by small sample sizes (de Hoog 2009, Wong 2011) and different inclusion criteria between groups (de Hoog 2009).

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
The Maeso (2010) SR briefly addressed complications associated with robotic and laparoscopic rectopexy procedures, noting that the incidence of complications, including postoperative constipation or incontinence, was similar between groups.

Subsequently Published Studies (August 2009 to 2012)
Both of the identified studies (de Hoog 2009; Wong 2011) report that the incidence of complications was similar between robotic, laparoscopic, and open surgical groups. The Wong (2011) study notes that there were no reported deaths in either the robotic or laparoscopic surgical groups.

Overall Summary and Limitations of the Evidence
Low strength evidence consistently suggests that robotic, laparoscopic and open rectopexy procedures were similar in terms of complication incidence.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs were identified that addressed this key question.

Individual Study Search Results (January 2002 to 2012)
No studies were identified that addressed this key question.

Overall Summary and Limitations of the Evidence
There is no evidence as to the differential efficacy or safety of robotic rectopexy compared to other methods of rectopexy across sub-groups.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
Maeso (2010) briefly reports that the costs associated with robotic rectopexy are €600 higher than those of laparoscopic rectopexy. However, the details of what this cost estimate includes were not provided.

Individual Study Search Results (January 2002 to 2012)
No studies were identified that addressed this key question.

Overall Summary and Limitations of the Evidence

There is low strength of evidence indicating that robotic rectopexy was more expensive than laparoscopic surgery. However, these findings are limited because the details of this cost estimate and how it was formulated were not described.

Roux-en-Y Gastric Bypass

One SR (Maeso 2010) and three subsequently published studies were identified that compared robotic Roux-en-Y gastric bypass to the laparascopic procedure.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

The Maeso SR (2010) identified one RCT and three non-randomized studies that compared robotic Roux-en-Y gastric bypass to the laparoscopic procedure for the treatment of morbid obesity. The RCT was rated as good quality and two of the other studies did not compare baseline characteristics so that selection bias could not be assessed. Sample sizes varied from 20 to 161 and follow-up time periods were not specified.

The Maeso SR performed a meta-analysis that found no significant differences in operative time between groups (MD 10.12m, 95% CI -69.86 to 90.11, NS) but greater odds of conversion among those in the robotic group (OR 9.46, 95% CI 1.72 to 52.15) when compared to the laparoscopic group (Maeso 2010).

Subsequently Published Study Results

Three retrospective studies were identified which addressed this key question (Ayloo 2011, Park 2011, Hagen 2011) using the same comparative groups. All three studies were of poor quality. The Ayloo study used non-contemporaneous controls and those in the robotic group were younger. The Park study had a high dropout rate and the assignment to surgical technique was unspecified. The Hagen study was limited by baseline differences between groups (healthier patients in robotic group as determined by ASA score) and the potential for conflict of interest (authors provided consulting or worked for the device manufacturer).

Between laparoscopic and robotic groups, surgical outcomes were mixed for comparisons across the three studies of operating times, LOS, blood loss, and conversions. Weight loss outcomes at 12 months noted not statistically significant differences between groups in either study.

Between open and robotic groups, Hagen (2011) reported shorter ICU stay (2.0 days vs. 0.2 days, $p<0.0001$) and shorter total LOS (10.9 days vs. 7.4 days, $p<0.0001$).

Overall Summary and Limitations of the Evidence

There was moderate strength of evidence that robotic Roux-en-Y gastric bypass was associated with higher odds of operative conversion than laparoscopic gastric bypass, but was similar in terms of operative duration. The conversions from robotic surgery were primarily to open approach with a few converted to conventional laparoscopic approach. There were no conversions from the laparoscopic primary procedures. There was low strength of evidence that robotic Roux-en-Y gastric bypass was associated with shorter ICU and hospital stays than open surgery.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

The odds of complications with robotic surgery vs. laparoscopic in the meta-analysis results were: OR = 0.58; 95% CI 0.21, 1.64 (NS). The complications were not specified.

Subsequently Published Study Results

Overall, the complication rates in the three subsequent studies (Ayloo 2011, Park 2011, Hagen 2011) were mixed or not significantly different between the intervention groups. Hagen (2011) reported that the robotic group had significantly lower probability of anastomotic leaks (4.0% vs. 0%, p=0.0349) and anastomotic strictures (6.8% vs. 0%, p=0.0002) than the laparoscopic group. Additionally, laparoscopic patients were more likely than robotic patients to be converted to open surgery (4.9% vs. 1.4%, p=0.0388), and to have reoperations (4.0% vs. 0.7%, p=0.0349). The same study found no significant differences between open surgery and robotic surgery on these outcomes (Hagen 2011).

Overall Summary and Limitations of the Evidence

There was low strength of evidence that complications were similar between laparoscopic and robotic procedures. Although one study found significant differences in complications between the laparoscopic and robotic groups, the study had substantial potential for bias in favor of the robotic group. Additionally, the strength of evidence that complications were similar between open and robotic Roux-en-Y gastric bypass was low.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

This SR did not address this key question.

Subsequently Published Study Results

One study was identified (Sanchez 2005) that reported a sub-group analysis for this procedure. This was a RCT (N=50) comparing robotic to laparoscopic Roux-en-Y gastric bypass procedures for the treatment of morbid obesity and evaluated these groups by BMI. This study was quality

rated as good. The baseline characteristics of both groups were not significantly different and there were no follow-up periods.

The surgical outcomes were reported as follows (favoring the robotic group):

- Reduced operative times (130.8 mins vs. 149.4 mins, *P*<0.001);
- Reduced operative time/BMI (expressed as mins per BMI) (2.94 vs. 3.47, *P*=0.02);
- Reduced operative times in patients with BMI >43 kg/m^2 (123.5 mins vs. 153.2 mins, *P*=0.009); and
- Reduced operative time/BMI in patients with BMI >43 kg/m^2 (2.49 vs. 3.24, *P*=0.009).

Overall Summary and Limitations of the Evidence

There was low strength of evidence that robotic had shorter operative time than laparascopic Roux-en Y, particularly as the degree of obesity increased.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

This key question was addressed in narrative of the SR and not included in the meta-analysis. The cost of robotic vs. laparoscopic Roux-en-Y gastric bypass procedures was €1,000 more expensive in one of the included studies. This cost figure was not defined.

Subsequently Published Study Results

One subsequently published study compared costs of robotic Roux-en-Y gastric bypass surgery to pure laparoscopic and open procedures (Hagen 2011). The cost analysis in Hagen was limited by poor quality evidence that informed the analysis, use of only direct costs, unknown source of cost inputs, and potential generalizability issues, as the data were collected in Switzerland. Overall, the Hagen analysis (2011) reported that robotic surgery was associated with lower costs compared to laparotomy and laparoscopic procedures ($19,363 vs. $23,000 vs. $21,697).

Overall Summary and Limitations of the Evidence

There is low strength of evidence that robotic gastric bypass surgery costs more than laparoscopic gastric bypass. Although one cost analysis was identified that reported lower costs for robotic surgery, the study possessed substantial limitations that could potentially bias results in favor of the robotic group.

Sacrocolpopexy

One SR (Reza 2010) and five subsequently published studies were identified that compare robotic sacrocolpopexy to open sacrocolpopexy procedures.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

Reza (2010) identified one prospective cohort study (n=178) that used historical controls to compare robotic sacrocolpopexy to open sacrocolpopexy (Geller 2008). Since evidence findings were limited to one study, a meta-analysis was not performed. The good quality Reza review assessed the quality of the Geller study, noting that the study was not randomized, or blinded, but had a clear objective. No other quality indicators were called out by the Reza review.

Reza reports that, according to the sole Geller study, robotic sacrocolpopexy was associated with significantly less blood loss (109 mL vs. 225 mL, $p<0.001$), shorter LOS (1.3 d vs. 2.7 d, $p<0.001$), and longer surgical duration (328 m vs. 225 m, $p<0.001$) compared to open sacrocolpopexy.

Subsequently Published Studies (October 2009 to 2012)

The MEDLINE® search identified five comparative studies addressing robotic sacrocolpopexy for treatment of vaginal or uterine prolapse (Paraiso 2011; Patel 2009, Seror 2011; Tan-Kim 2011; White 2009). One study (Paraiso 2011) was a fair quality RCT (n=78) that was limited by its small sample size. The other four studies were small (n=15, n=30, n=67, and n=78), poor quality retrospective cohort studies (Patel 2009; Tan-Kim 2011; White 2009) and a prospective cohort study (Seror 2011).

Patients undergoing the robotic procedure did not statistically significantly differ from those undergoing open (Patel 2009) or laparoscopic (Paraiso 2011; Patel 2009; Seror 2011; Tan-Kim 2011; White 2009) in terms of LOS. Paraiso (2011) also reported similar time to return to normal activities and reported limitation in activity between laparoscopic and robotic groups. Additionally, White (2009) reported similar symptom relief between laparoscopic and robotic groups.

Paraiso (2011) reported significantly less pain and less use of NSAIDs among those undergoing the pure laparoscopic procedure compared to the robotic group ($p\leq0.04$). However, Seror (2011) notes statistically similar use of pain medicines between laparoscopic and robotic groups.

Findings on operating time and estimated blood loss were mixed across studies. Two studies, including the fair quality RCT (Paraiso 2011) and a lower quality cohort (Tan-Kim 2011) noted shorter operating time in the laparoscopic group (Paraiso 2011). Other low-quality cohort studies found no statistically significant differences between laparoscopic and robotic groups (Patel 2009; Tan-Kim 2011; White 2009). The only study to compare robotic sacrocolpopexy to open surgery also found no statistically significant differences in operating time (Patel 2009). One study reported less blood loss in the robotic group (55 mL vs. 280 mL, $p=0.03$, Seror 2011)

compared to the laparoscopic group, while two other cohorts reported non-significant differences (Patel 2009; White 2009).

Overall Summary and Limitations of the Evidence

Low strength evidence indicates that robotic and laparoscopic sacrocolpopexy resulted in statistically similar activity limitation and time until return of normal activity level. Findings on perioperative outcomes, such as operating time, LOS, and EBL, and symptom relief, were mixed. Evidence comparing robotic sacrocolpopexy to open surgery was also mixed. Although the Geller study reported in the Reza review reported shorter LOS, less blood loss, and longer surgical duration among the robotic group, the Patel study found no significant differences between groups on these outcomes. Given the small sample size of the Patel study (n=5 in each arm), it was likely underpowered to detect such differences. The strength of evidence comparing robotic sacrocolpopexy to open surgery is very low.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

Reza reports that, according to the sole Geller study, robotic sacrocolpopexy was associated with significantly higher incidence of postoperative fever compared to open surgery (Reza 2010).

Subsequently Published Studies (October 2009 to 2012)

Three of the identified comparative studies reported briefly on the safety and incidence of adverse events in robotic sacrocolpopexy as compared to open and laparoscopic procedures.

Several statistically non-significant findings were reported. Among these were non-significant differences in:

- Intraoperative complications between robotic and laparoscopic sacrocolpopexy (Paraiso 2011; Tan-Kim 2011; White 2009);
- Postoperative complications between robotic and laparoscopic sacrocolpopexy (Paraiso 2011; Tan-Kim 2011; White 2009);
- Reoperation between robotic and laparoscopic sacrocolpopexy (White 2009).

Overall Summary and Limitations of the Evidence

The strength of the evidence on complications arising from robotic, laparoscopic and open sacrocolpopexy is low. Compared to open surgery, robotic surgery was reported as having increased incidence of postoperative fever. Additionally, several studies have found that the incidence of complications is similar between robotic and laparoscopic methods.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Subsequently Published Studies (October 2009 to 2012)
None of the subsequently published studies addressed this key question.

Overall Summary and Limitations of the Evidence
There is no evidence on differential efficacy or safety issues across sub-groups for robotic, laparoscopic, or open sacrocolpopexy.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
Three of the identified studies described above (Paraiso 2011; Patel 2009; Tan-Kim 2011) addressed the comparative costs of robotic sacrocolpopexy and laparoscopic or open sacrocolpopexy. Additionally, a cost-minimization analysis (Judd 2010) was also identified that analyzed a hypothetical cohort of women with pelvic organ prolapse using data from the Geller (2008) study identified in the Reza SR (2010). All of the identified cost analyses were rated as poor quality, primarily because the evidence used to inform the analyses was of poor quality.

Paraiso reported that the total healthcare system costs associated with the laparoscopic procedure (approximately $14,342) were significantly less than those of the robotic procedure (approximately $16,278), though costs of hospitalization and six-week post-operative care were the same. Paraiso notes that the additional cost for the robotic procedure is primarily due to additional operating room costs ($1667, 95% CI: $448 to $2885). Surgical costs and hospital costs were also compared between robotic and laparoscopic procedures in the Tan-Kim study (2011). In that study, surgical costs were higher in the robotic group than in the laparoscopic group, but hospital costs were similar (Tan-Kim 2011). According to the Patel analysis, total instrument costs were lower for the laparoscopic group than the robotic group because of higher disposable instrument costs for the robotic procedure (Patel 2009).

Overall Summary and Limitations of the Evidence
There is low strength evidence that laparoscopic sacrocolpopexy was associated with lower total healthcare system costs than robotic sacrocolpopexy. These findings may be limited by potential bias in favor of the laparoscopic procedure if surgeons performing robotic procedures had not yet attained complete proficiency. However, this bias may be balanced by the fact that the highest quality analysis, performed in the Paraiso study, did not account for purchase or

maintenance of the *da Vinci* system in its cost analysis. There is very low strength of evidence that robotic sacrocolpopexy has higher total charges compared to open procedures.

Splenectomy

One study was identified that compared robotic-assisted splenectomy to laparoscopic splenectomy.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The MEDLINE® search identified one retrospective cohort study comparing robotic to laparoscopic splenectomy for treatment of hematologic disorders (Bodner 2005). This study was a small (n=12) retrospective cohort rated as poor quality, primarily because of small sample size and observational study design. However, the study did possess several strengths for a study of its type. Notably, patients were matched by age, BMI, ASA score (a measure of preoperative physical fitness), and preoperative platelet levels. Additionally, the same surgeon performed all procedures.

The sole study identified did not report statistically significant findings in favor of robotic surgery. However, Bodner (2005) reported that operating time for robotic splenectomy was significantly longer than for laparoscopic splenectomy (154 m robotic vs. 127 m laparoscopic, $p<0.05$, Bodner 2005). The two groups did not have significant differences in terms of LOS or EBL (Bodner 2005).

Overall Summary and Limitations of the Evidence
There is very low strength evidence that laparoscopic splenectomy was associated with shorter operating time as compared to robotic splenectomy. Additionally, there is low strength of evidence that LOS and EBL were similar between surgical modalities.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Bodner (2005) study reported that differences between robotic and laparoscopic splenectomy in complication incidence, including conversions to open surgery, were not statistically significant.

Overall Summary and Limitations of the Evidence
The strength of the evidence on complications arising from robotic and laparoscopic splenectomy is very low due to retrospective study design and small sample size. However, the evidence suggests that the incidence and severity of complications was similar between the two approaches.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Bodner (2005) study did not address sub-populations.

Overall Summary and Limitations of the Evidence
There is no evidence on differential efficacy or safety issues across sub-groups for robotic or laparoscopic splenectomy.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
Bodner (2005) reports robotic procedures had higher average procedural costs than laparoscopic procedures ($6,927 vs. $4,084, $p<0.05$). The cost difference was attributed to the longer operation time, use of special instruments, and disposable supply costs in the robotic group. Its cost assessment did not include the initial cost of the robotic system, but maintenance costs were included.

Overall Summary and Limitations of the Evidence
There is very low strength evidence that robotic splenectomy incurred higher costs than laparoscopic splenectomy, though the analysis relied primarily on itemized charges reported by a single institution's billing department.

Thymectomy

Two studies were identified that compare robotic thymectomy to thoracoscopic or open surgery.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

The MEDLINE® search identified two comparative studies addressing robotic thymectomy for treatment of myasthenia gravis (Cakar 2007; Ruckert 2011). Both studies were retrospective cohort studies that used historic controls.

Two studies (total n=172) report on robotic thymectomy compared to conventional thoracoscopic surgery (Ruckert 2011) or open surgery (Cakar 2007). The earlier Cakar study was very small (n=19) and was rated as poor quality because of the small sample size, noncontemporaneous controls, and differences between groups in terms of disease severity, which may have biased the results in favor of the robotic procedure. The more recent Ruckert (2011) study was a larger (n=153) cohort, but was also rated as poor quality because there were no indications of estimate precision or statistical significance of findings, and noncontemporaneous controls were used.

Robotic surgery was associated with increased frequency of remission at follow-up compared to both open surgery (80% endoscopic vs. 100% robotic, no p-value given, Cakar 2007) and thoracoscopic surgery (39.3% endoscopic vs. 20.3% robotic, p=0.01, Ruckert 2011). Additionally, robotic surgery was associated with shorter LOS compared to open surgery (5 days robotic vs. 10 days open, p<0.05). Ruckert (2011) did not report LOS between robotic and thoracoscopic procedures.

Compared to the open procedure, robotic thymectomy was associated with longer operating times (154 m robotic vs. 110 m open, Cakar 2007). Operating times between the thoracoscopic procedure and robotic procedure were similar (187 ± 48 m robotic vs. 198 ± 48 m thoracoscopic, no p-value given, Ruckert 2011).

Several statistically non-significant findings were reported. Among these were non-significant differences in:

- Bleeding incidence between robotic and thorascopic procedures (Ruckert 2011);
- Phrenic nerve resection between robotic and thoracoscopic procedures (Ruckert 2011); and
- EBL between robotic and open procedures (Cakar 2007).

Overall Summary and Limitations of the Evidence

The overall strength of evidence is low that robotic thymectomy was associated with clinical improvement at follow-up and shorter LOS as compared to thoracoscopic or open thymectomy. There is low strength evidence for longer operative times for robotic vs. open procedures. The strength of evidence is low that EBL was similar among treatment groups.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

The two comparative studies addressing robotic thymectomy (Cakar 2007; Ruckert 2011) report briefly on the safety and incidence of adverse events as compared to open and endoscopic thymectomy procedures.

Several statistically non-significant findings were reported. Among these were non-significant differences in:

- Conversion to sternotomy between robotic and thoracoscopic procedures (Ruckert 2011);
- 30-day mortality between robotic and thoracoscopic procedures (Ruckert 2011); and
- Major complications between robotic and open procedures (Cakar 2007).

Additionally, the very small Cakar study reported differences in adverse outcomes between open and robotic groups, but the statistical significance of these findings was not tested due to the small sample size. These findings suggested that the robotic procedure may have had fewer postoperative complications, as well as a lower incidence of reoperation, compared to the open procedure (Cakar 2007).

Overall Summary and Limitations of the Evidence

The strength of the evidence on complications arising from robotic, endoscopic and open thymectomy is low. However, this limited evidence suggests that the incidence and severity of complications was similar among all three surgical approaches.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings

No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)

The two identified studies (Cakar 2007, Ruckert 2011) did not address sub-populations.

Overall Summary and Limitations of the Evidence
There is no evidence on differential efficacy or safety issues across sub-groups for robotic, endoscopic, or open thymectomy.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The two identified studies (Cakar 2007, Ruckert 2011) did not address costs.

Overall Summary and Limitations of the Evidence
There is no evidence on comparative costs of robotic, endoscopic or open thymectomy.

Thyroidectomy

Five studies were identified that compared robotic thyroidectomy to endoscopic or open surgery.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The MEDLINE® search identified five comparative studies that addressed robotic thyroidectomy (Kim 2011b; Lang 2011; Lee 2010; Lee 2011b; Lee 2011c). Of these, four were retrospective cohort studies (Kim 2011b; Lang 2011; Lee 2010, Lee 2011c) and one was a prospective cohort study (Lee 2011b).

Five studies (N=1,102) compared robotic thyroidectomy to conventional endoscopic surgery (Kim 2011b, Lang 2011; Lee 2010a) or open surgery (Kim 2011b; Lee 2010, Lee 2011b) for the treatment of thyroid cancer, goiter, or hyperthyroidism. Individual sample sizes ranged from 46 to 411, while follow-up time ranged from zero to six months. Two studies reported some significant baseline differences between groups: the robotic groups were younger (Lee 2011b, Kim 2011), were more likely to be female (Kim 2011b; Lee 2011b), had lower BMI (Kim 2011b; Lee 2011b), and had less advanced disease (Lee 2011b). Treatment groups were otherwise comparable at baseline. Four of the five identified studies (Kim 2011b; Lang 2011; Lee 2010, Lee 2011b) were rated as poor quality primarily due to retrospective design, potential for selection bias (magnitude and direction unknown), or lack of follow-up. The fifth study (Lee 2011c) was a

larger study (n=411) rated fair, though baseline differences between treatment groups may have produced moderate bias in favor of the robotic procedure.

Among the identified studies, only the Lee (2010) study reported findings significantly favoring robotic surgery. In that study, patients undergoing robotic surgery were found to have better swallowing impairment index scores both one week (p=0.001) and three months (p=0.007) postoperatively (Lee 2010). Additionally, patients undergoing robotic surgery reported greater satisfaction with cosmetic results at three months than those undergoing open surgery (p<0.001) (Lee 2010).

Two studies found open procedures resulted in significantly shorter operating times (Kim 2011b; Lee 2010) compared to the robotic procedure. Compared to endoscopic surgery, robotic surgery was significantly associated with longer operating times in one study (3:16 ± 0:45 hrs robotic vs. 2:16 ± 0:31 hrs endoscopic, p<0.001, Kim 2011) but significantly shorter times in another (110.1 ± 50.7 m robotic vs. 142.7 ± 52.1 m endoscopic, p=0.041, Lee 2010). Both studies were poor quality cohort studies.

Several statistically non-significant findings were reported. Among these were:

- LOS between open and robotic groups (Kim 2011b; Lee 2010);
- LOS between endoscopic and robotic groups (Kim 2011b; Lang 2011; Lee 2011b);
- Markers of completeness of thyroid tissue removal (i.e., surgical completeness): thyroglobulin (Tg) levels and radioactive iodine (RAI) uptake between robotic and open groups (Lee 2011b; Lee 2011c);
- Number of lymph nodes retrieved between robotic, endoscopic, and open groups (Kim 2011b);
- Tumor recurrence at 6 to 12 months between robotic and open groups (Lee 2010);
- EBL between robotic and open groups (Lee 2010) and robotic and endoscopic groups (Lee 2011b);
- Analgesic use and pain scores between robotic and open groups (Lee 2010); and
- Voice handicap index between robotic and open groups (Lee 2010).

Overall Summary and Limitations of the Evidence

There is low-strength evidence that robotic thyroidectomy and endoscopic or open thyroidectomy are similar in terms of most outcomes. While there was a quantity of research for this procedure, most of the studies were poor and subject to substantial biases. Operative times were longer for robotic procedures than open procedures, though evidence comparing operative times in robotic thyroidectomy to endoscopic thyroidectomy was mixed. In terms of patient-important outcomes (ease of swallowing, cosmetic satisfaction), robotic surgery appeared to yield more favorable outcomes. However, these outcomes were only assessed by one moderate quality study (Lee 2011b) and future studies may further inform these outcomes.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The MEDLINE® search identified five comparative studies addressing complications of robotic thyroidectomy (Kim 2011b; Lang 2011; Lee 2010; Lee 2011b; Lee 2011c). Four studies reported that the incidence of complications were comparable between groups (Kim 2011b; Lang 2011; Lee 2010; Lee 2011b). One study (Lang 2011) reported findings related to complication severity, noting that more patients undergoing robotic surgery had permanent nerve damage from the procedure when compared to those undergoing endoscopic thyroidectomy, though fewer had temporary nerve damage. However, these differences were not statistically significant. Three studies reported that incidence of open surgery conversion was similar between robotic and endoscopic groups (Kim 2011b; Lang 2011; Lee 2010).

Overall Summary and Limitations of the Evidence
The strength of the evidence for complications arising from robotic, endoscopic and open thyroidectomy is low. However, consistent evidence suggests that the incidence and severity of complications were similar among all three surgical approaches.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The MEDLINE® search identified one comparative study that evaluated the relationship between surgeon experience and operative time for robotic thyroidectomy and endoscopic thyroidectomy (Lee 2010). This small, retrospective study reported that the surgeon learning curve was shorter for the robotic procedure than the endoscopic procedure, in that operative times steadied after 35 to 40 robotic procedures versus 55 to 60 endoscopic procedures (Lee 2010).

Overall Summary and Limitations of the Evidence
The overall strength of the evidence for surgeon learning curves between surgical modalities is very low. Given that the same surgeon was concurrently performing both procedures and the robotic group was more likely to have benign lesions and less likely to have lymph node dissection, these findings are substantially vulnerable to potential biases.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The MEDLINE® search identified one poor quality comparative study that discussed the costs associated with robotic and endoscopic thyroidectomy (Lang 2011), reporting that the robotic procedure costs were approximately $1,300 greater than endoscopic surgery costs. The authors did not provide any details of the costs included in this estimate, or whether these costs were direct or indirect.

Overall Summary and Limitations of the Evidence
Very limited evidence was identified regarding the differential cost between robotic thyroidectomy and endoscopic thyroidectomy. As such, the strength of evidence is very low.

Trachelectomy

One study was identified that compared robotic trachelectomy to open radical trachelectomy.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The MEDLINE® search identified one small retrospective cohort comparing 37 women undergoing robotic (n=12) or open (n=25) radical trachelectomy (Nick 2012) for treatment of early cervical cancer while seeking to maintain their fertility. This study was rated as good quality. The treatment groups had similar baseline characteristics, with no statistically significant differences in age, parity, tumor stage or histology.

The Nick study found shorter LOS (1 d robotic vs. 4 d open, $p<0.001$) and lower EBL (62.5 mL robotic vs. 300 mL open, $p=0.0001$) in the robotic group than in the open group (Nick 2012). No statistically significant differences were noted between intervention groups regarding operating times or transfusion rates.

Overall Summary and Limitations of the Evidence
There is very low strength of evidence that robotic-assisted trachelectomy resulted in shorter LOS and reduced EBL when compared to the open approach.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Nick study (2012) reported that the differences between intervention groups in less than 30 day morbidity, incidence of fever, urinary tract infection, or urinary retention were not statistically significant. The overall morbidity incidence greater than 30days was greater in the open surgery group, 13% vs. 58% (p=0.07), but this difference did not achieve statistical significance. However, the rate of conversion to hysterectomy was significantly higher in the robotic surgery group, 33% vs. 4% (p=0.03).

Overall Summary and Limitations of the Evidence
There is very low strength of evidence that the postoperative morbidities (fever, UTI, cervical stenosis, menstrual bleeding) of both robotic and open trachelectomy was relatively similar between both groups. However, there is a significantly higher rate of conversion to hysterectomy in the robotic group.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Nick study (2012) did not address sub-populations.

Overall Summary and Limitations of the Evidence
There is no evidence on differential efficacy or safety issues across sub-groups for robotic or open trachelectomy.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Nick study (2012) did not address costs for this procedure.

Overall Summary and Limitations of the Evidence
There was no evidence identified regarding comparative costs of robotic vs. open trachelectomy.

Vesico-vaginal fistula

One study was identified that compared robotic vesico-vaginal fistula repair to the open procedure.

KQ1: What is the evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open or laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The MEDLINE® search identified one small retrospective cohort comprised of 12 individuals undergoing robotic vesico-vaginal fistula (VVF) repair who were case-matched to 20 controls undergoing the same procedure via laparotomy (Gupta 2010). This study was quality rated as poor. The treatment groups had similar baseline characteristics, with no statistically significant differences in age, parity, previous delivery location, cause of fistula, history of surgical repair, or fistula size.

The Gupta study found shorter LOS (3.1 days robotic vs. 5.6 days open, $p<0.05$) and lower EBL (88 mL robotic vs. 170 mL open, $p<0.05$) in the robotic group than in the open group. Operating time and surgical success rate was not statistically significantly different between groups.

Overall Summary and Limitations of the Evidence
The strength of evidence for all comparators and outcomes is very low. Although the strength of evidence on the comparative effectiveness of robotic VVF repair is very low, robotic VVF repair was associated with short hospital stays and lower blood loss compared to open VVF repair. No differences in operating time or surgical success rate were reported. However, these findings are limited to a single study, itself limited by retrospective design, small sample size, and reliance on surrogate outcomes. Patient-important outcomes (e.g. time to return to normal activity) were not measured.

KQ2: For robotic assisted surgery, what is the evidence of the severity and incidence of safety or adverse event concerns compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Gupta study (2010) reported that the difference in complication incidence between robotic and open VVF repair was not statistically significant. Two cases, both in the robotic group, reported complications: one with a wound infection and one with dyspareunia.

Overall Summary and Limitations of the Evidence
The strength of the evidence on complications arising from robotic and open VVF repair is very low due to retrospective study design, small sample size, and insufficient follow-up. However, the evidence suggests that the incidence and severity of complications was similar between the two approaches.

KQ3: What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Gupta study (2010) did not address sub-populations.

Overall Summary and Limitations of the Evidence
There is no evidence on the differential efficacy or safety issues across sub-groups for robotic or open VVF repair.

KQ4: What is the evidence of cost and cost-effectiveness of robotic surgery compared with open or laparoscopic approaches?

Systematic Review and Technology Assessment Findings
No SRs or TAs addressed this key question.

Individual Study Search Results (January 2002 to 2012)
The Gupta study (2010) did not address costs.

Overall Summary and Limitations of the Evidence
There is no evidence on comparative costs of robotic vs. open VVF repair.

Guidelines Summary

Summary of Guidelines and Quality Assessment
The search for clinical practice guidelines identified 14 guidelines that were published within the past five years and pertained to robotic surgery: American Urological Association (AUA 2010), European Association of Urology (EAU 2011), National Comprehensive Cancer Network (NCCN 2011; 2012a; 2012b), NICE (2006; 2008a; 2008b; 2008c; 2009a; 2009b), Society of American Gastrointestinal and Endoscopic Surgeons (SAGES 2010, 2011) and Spanish National Health Service (SNHS 2008). The guidelines are summarized below and described in more detail in Appendix E. Appendix F describes each guideline's quality assessment rating and Appendix G has the guideline quality assessment tool.

Guidelines addressing the use of robotic technology across procedures are mixed. All recommendations with the exception of NICE (2006; 2008c) and SAGES (2011, 2010) are based primarily on whether the procedure is recommended for the indication rather than the specific

use of robotic technology. In other words, in all other guidelines if the laparoscopic procedure is recommended, then robotic is also included.

Recommendations are presented in Table 9. For the treatment of benign prostatic hyperplasia, one poor quality guideline (AUA 2010) recommends laparoscopic prostatectomy and the use of robotic technology is included in the recommendation. Laparoscopic prostatectomy for benign prostatic obstruction with or without robotic assistance is not recommended by one fair quality guideline (NICE 2008a). The treatment of prostate cancer with laparoscopic prostatectomy, which could include robotic assistance, is recommended in two fair, and one good quality guidelines (NICE 2008b; Spanish NHS 2008; NCCN 2012a). One fair quality guideline (NICE 2006) does not recommend the use of robotically assisted laparoscopic prostatectomy. Two fair quality guidelines (EAU 2011; NICE 2009) recommend laparoscopic cystectomy with or without robotic assistance for the treatment of bladder cancer. One of those guidelines (EAU 2011) considered the procedure as feasible but still investigational.

Guidelines for seven additional procedures were found including five recommendations supporting the use of robotic assistance. Fair quality guidelines support the use of robotic techniques in the following procedures:

- Esophagogastrectomy in the treatment of esophageal and esophagogastric junction cancers (NCCN 2011);
- Radical and partial nephrectomy in the treatment of kidney cancer (NCCN 2012b);
- Pyeloplasty for pelviureteric junction obstruction (NICE 2009b);
- Fundoplication for GERD (SAGES 2010); and
- Pelvic lymph node dissection for prostate cancer (NCCN 2012).

A weak recommendation for the use of robotic assistance in myotomy for esophageal achalasia is included in a fair quality guideline (SAGES 2011). A fair quality guideline on coronary artery bypass grafting for coronary artery disease (NICE 2008c) recommends against endoscopic robotically assisted procedures.

Table 9. Guideline Summary

Author, year	Condition	Evidence Base	Quality	Recommendation
Prostatectomy				
American Urological Association, 2010	benign prostatic hyperplasia	Systematic review and panel consensus	Poor	When laparoscopic prostatectomy is indicated, use of robotic technology is included in recommendation
NICE, 2008a	benign prostatic obstruction	Systematic review	Fair	Laparoscopic prostatectomy with or without computer (robotic) assistance is not recommended
NICE, 2008b	prostate cancer	Systematic review	Fair	When laparoscopic prostatectomy is indicated, use of robotic technology is

Author, year	Condition	Evidence Base	Quality	Recommendation
				included in recommendation
NICE, 2006	prostate cancer	Systematic review	Fair	Robotically assisted laparoscopic prostatectomy is a development of this procedure but it is not recommended
Spanish NHS, 2008	prostate cancer	Systematic review	Good	When laparoscopic prostatectomy is indicated, use of robotic technology is included in recommendation
National Comprehensive Cancer Network (NCCN), 2012a	prostate cancer	Systematic review	Fair	Laparoscopic & robotic-assisted radical prostatectomy are used commonly
Cystectomy				
European Association of Urology, 2011	bladder cancer	Systematic review	Fair	Laparoscopic and robotic-assisted laparoscopic cystectomy is feasible but still investigational
NICE, 2009a	bladder cancer	Systematic review	Fair	Laparoscopic cystectomy recommended including with computer (robotic) assistance.
Other procedures				
NCCN, 2011	Esophagogastrectomy for esophageal and esophagogastric junction cancers	Systematic review	Fair	Robotic considered acceptable operative approach
NCCN, 2012b	Radical and partial nephrectomy for kidney cancer	Systematic review	Fair	Open, laparoscopic or robotic surgical techniques may be used
NICE, 2008c	Coronary artery bypass grafting (CABG) for coronary artery disease	Systematic review	Fair	Totally endoscopic robotically assisted procedure not recommended
NICE, 2009b	Pyeloplasty for pelviureteric junction obstruction	Systematic review	Fair	When laparoscopic pyeloplasty is indicated, use of robotic technology is included in recommendation
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), 2011	Myotomy for esophageal achalasia	Systematic review	Fair	Weak recommendation for the use of robotic assistance
SAGES, 2010	Fundoplication for GERD	Systematic review	Fair	Robotic –assisted surgery is recommended
NCCN, 2012a	Pelvic lymph node dissection for prostate cancer	Systematic review	Fair	Use an open, laparoscopic or robotic technique

Policy Summary

This section summarizes coverage policies by Medicare, Aetna, Regence Blue Cross Blue Shield (BCBS), and Group Health addressing robotic assisted surgery. Appendix H provides further detail and direct web links to each policy reviewed.

Medicare
Medicare has not issued a national or local coverage determination for robotic assisted surgery. Since 2005, Medicare has identified robotic assisted surgery as a non-reportable code (S2900), and does not provide additional reimbursement for the use of robotic surgical techniques. Reimbursement is based on the underlying surgical procedure performed.

Aetna
No policies identified for robotic assisted surgery.

Group Health
No policies identified for robotic assisted surgery.

Regence BCBS Washington
Regence BCBS Washington does not provide additional reimbursement for robotic assisted surgery. Reimbursement is based on the primary procedure performed. Regence has not set forth clinical coverage criteria for the use of robotic assisted surgery.

Overall Summary

This report presents evidence about the application of robotic assisted surgery for over 25 different individual types of procedures, including prostatectomy, hysterectomy, nephrectomy, various cardiac surgery procedures, adjustable gastric banding, adnexectomy, adrenalectomy, cholecystectomy, various types of colorectal surgery, cystectomy, esophagectomy, fallopian tube reanastomosis, fundoplication, gastrectomy, Heller myotomy, ileovesicostomy, liver resection, lung surgery, oropharyngeal surgery, pancreatectomy, pyeloplasty, rectopexy, Roux-en-Y gastric bypass, sacrocolpoplexy, splenectomy, thymectomy, thyroidectomy, trachelectomy, and vesico-vaginal fistula. Overall, there was a lack of evidence to answer all key questions for each procedure. Generally there is low to moderate strength of evidence that robotic assisted procedures are associated with improved outcomes such as shorter hospital stays, reduced blood loss and transfusion for several procedures (e.g. prostatectomy, hysterectomy, nephrectomy, cystectomy). Where it has been examined, operative times using robotic assistance are generally longer than for conventional surgeries. There is a general lack of study for patient-centered outcomes (e.g., quality of life, longer survival). Many studies are limited by small sample sizes, retrospective nature of data collection and analysis, dissimilar of control groups, and inadequate control of potential confounders.

Many studies reported no or few types of adverse events and harms regarding the use of robotic assistance for these procedures and the overall strength of evidence for harms was very low for most procedures with the exception of prostatectomy, hysterectomy, nephrectomy, fundoplication, and sacrocolpoplexy. Where it was reported, robotic assisted surgery generally had similar complication rates to laparoscopic procedures (e.g. prostatectomy, nephrectomy, fundoplication) or to open procedures (e.g. hysterectomy, gastrectomy, vesico-vaginal fistula).

There were insufficient data to address the question of differential safety or efficacy of robotic assisted procedures for subgroups of patients by gender, age, patient characteristics or

comorbidities, or type of payer for nearly all procedures. Where it was studied there were data indicating that there is a "learning curve" for use of robotic equipment and that some outcomes were improved with increasing levels of experience (e.g. operative time, LOS, and complication rates for robotic prostatectomy).

There are start up equipment and training costs for robotic surgery and most of the included economic evaluations offered insufficient or low overall strength of evidence to address economic questions. In nearly all cases, the costs of robotic procedures were higher than comparable laparoscopic or open procedures. Some costs may be offset if the procedure results in shorter hospital LOS and the center has sufficient procedural volume over which to amortize equipment costs. Cost-effectiveness studies are hampered by lack of full information on all relevant outcomes and insufficient length of follow up to determine long term benefits and safety.

Nearly all relevant guidelines recommend that robotic surgery is a viable alternative when laparoscopic surgery is supported. However, there are some notable exceptions such as an active recommendation against robotic assisted CABG by NICE. There are no Medicare NCDs or LCDs for robotic-assisted surgery.

Appendix A. MEDLINE® Search Strategy

Database: Ovid MEDLINE®(R) and Ovid OLDMEDLINE®(R) <1946 to February Week 1 2012>
Search Strategy:

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1 exp Robotics/ (9390)
2 exp Surgical Procedures, Operative/ (2145324)
3 exp General Surgery/ (31224)
4 su.fs. (1427999)
5 2 or 3 or 4 (2708446)
6 1 and 5 (5468)
7 exp Surgery, Computer-Assisted/ (6902)
8 robot$.mp. (13004)
9 7 and 8 (1297)
10 6 or 9 (5547)
11 exp "Outcome and Process Assessment (Health Care)"/ (580943)
12 exp survival analysis/ (144692)
13 exp Mortality/ (242698)
14 mo.fs. (357802)
15 exp "Quality of Life"/ (95741)
16 exp "Activities of Daily Living"/ (44187)
17 exp "Costs and Cost Analysis"/ (160841)
18 exp Postoperative Complications/ (376177)
19 exp Intraoperative Complications/ (32412)
20 exp "Recovery of Function"/ (23041)
21 exp "Length of Stay"/ (49077)
22 exp Patient Readmission/ (6161)
23 exp Reoperation/ (59302)
24 10 and 11 (1231)
25 12 or 13 or 14 (562632)
26 10 and 25 (190)
27 15 or 16 (131810)
28 10 and 27 (105)
29 18 or 19 (397886)
30 10 and 29 (637)
31 20 or 21 (71487)
32 10 and 31 (340)
33 22 or 23 (65330)
34 10 and 33 (60)
35 10 and 17 (128)
36 24 or 26 or 28 or 30 or 34 or 35 (1772)
37 limit 36 to english language (1639)

38 limit 37 to humans (1606)
39 limit 38 to (controlled clinical trial or meta analysis or randomized controlled trial) (67)
40 random$.mp. (701391)
41 38 and 40 (141)
42 limit 38 to systematic reviews (69)
43 39 or 41 or 42 (200)
44 limit 43 to yr="2002 -Current" (198)
45 Comparative Study/ (1554044)
46 38 and 45 (359)
47 46 not 43 (290)
48 43 or 46 (490)
49 35 or 48 (568)
50 limit 49 to english language (558)
51 limit 50 to yr="2002 -Current" (537)

Appendix B. Excluded Studies

Study design not relevant

Abreu, A. L., Gill, I. S., & Desai, M. M. (2011). Zero-ischaemia robotic partial nephrectomy (RPN) for hilar tumours. *BJU International, 108*(6 Pt 2), 948-954. doi:http://dx.doi.org/10.1111/j.1464-410X.2011.10552.x

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Baek, J. H., Pastor, C., & Pigazzi, A. (2011). Robotic and laparoscopic total mesorectal excision for rectal cancer: A case-matched study. *Surgical Endoscopy, 25*(2), 521-525.

Baik, S. H., Ko, Y. T., Kang, C. M., Lee, W. J., Kim, N. K., Sohn, S. K., . . . Cho, C. H. (2008). Robotic tumor-specific mesorectal excision of rectal cancer: Short-term outcome of a pilot randomized trial. *Surgical Endoscopy, 22*(7), 1601-1608.

Balkhy, H. H., Wann, L. S., Krienbring, D., & Arnsdorf, S. E. (2011). Integrating coronary anastomotic connectors and robotics toward a totally endoscopic beating heart approach: Review of 120 cases. *Annals of Thoracic Surgery, 92*(3), 821-827.

Barbash, G. I., & Glied, S. A. (2010). New technology and health care costs--the case of robotic-assisted surgery. *New England Journal of Medicine, 363*(8), 701-704.

Benson, A. D., Kramer, B. A., Wayment, R. O., & Schwartz, B. F. (2010). Supracervical robotic-assisted laparoscopic sacrocolpopexy for pelvic organ prolapse. *Journal of the Society of Laparoendoscopic Surgeons, 14*(4), 525-530. doi:http://dx.doi.org/10.4293/108680810X1292446600806

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Bonaros, N., Schachner, T., Wiedemann, D., & Bonatti, J. (2010). Hot potatoes, million dollar coat hangers and advanced coronary surgery. *Cardiology, 115*(3), 184-185.

Boorjian, S. A., & Gettman, M. T. (2008). Advances in robotic prostatectomy. *Current Urology Reports, 9*(3), 250-256.

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Appendix C. MEDLINE® Search Dates by Procedure

Procedures and key questions with searches of the full date range (2002 to 2012) are highlighted in peach. Procedures and key questions highlighted in blue represent those with a SR or TA where subsequent search dates were limited.

Procedures	Review	MEDLINE® Beginning Search Dates		
		Key Questions 1 and 2	Key Question 3	Key Question 4
Adjustable gastric band	Maeso	Aug-09	2002	2002
Adnexectomy	Reza	Oct-09	2002	2002
Adrenalectomy	None	2002	2002	2002
Atrial septal repair	CADTH	Sep-11	2002	Sep-11
CABG	CADTH	Sep-11	2002	Sep-11
Cholecystectomy	Maeso	Aug-09	2002	2002
Colorectal resection	Maeso	Aug-09	2002	2002
Cystectomy	Thavaneswaran	Feb-09	2002	2011
Esophagectomy	Clark	Apr-10	2002	2002
Fallopian tube reanastomosis	Reza	Oct-09	2002	2002
Gastrectomy	Clark	Apr-10	2002	2002
Heller myotomy	Maeso	Aug-09	2002	2002
Hysterectomy	CADTH	Sep-11	2002	Sep-11
Ileovesicostomy	None	2002	2002	2002
Liver resection	None	2002	2002	2002
Lung surgery	None	2002	2002	2002
Mesorectal excision	None	2002	2002	2002
Mitral valve repair	CADTH	Sep-11	2002	Sep-11
Myomectomy	Reza	Oct-09	2002	2002
Nephrectomy	CADTH	Sep-11	2002	Sep-11

Procedures	Review	MEDLINE® Beginning Search Dates		
		Key Questions 1 and 2	Key Question 3	Key Question 4
Nissen fundoplication	Maeso	Aug-09	2002	2002
Oropharyngeal surgery	None	2002	2002	2002
Pancreatectomy	None	2002	2002	2002
Prostatectomy	CADTH	Sep-11	2002	Sep-11
Pyeloplasty	Thavaneswaran	Feb-09	2002	2002
Rectopexy	Maeso	Aug-09	2002	2002
Roux-en-Y gastric bypass	Maeso	Aug-09	2002	2002
Splenectomy	Maeso	Aug-09	2002	2002
Sacrocolpopexy	Reza	Oct-09	2002	2002
Thoracoscopic resection	None	2002	2002	2002
Thymectomy	None	2002	2002	2002
Thyroidectomy	None	2002	2002	2002
Trachelectomy	None	2002	2002	2002
Vesico-vaginal fistula repair	None	2002	2002	2002

Appendix D. Summary of Findings Tables by Procedure

Introduction

This summary of findings provides an overview of the strength of evidence for the use of robotic assisted surgery compared to open or laparoscopic surgeries. This summary of findings is intended to *supplement* the Washington Health Technology Assessment Program's *Robotic-Assisted Surgery* report. The findings presented in this document are in aggregate. For specific details and findings per procedure, please refer to the full report at http://www.hta.hca.wa.gov/documents/robotic_assisted_surgery_final_041812.pdf

Symbol Key

Strength of Evidence

⊕⊕⊕⊕	High
⊕⊕⊕O	Moderate
⊕⊕OO	Low
⊕OOO	Very Low

Outcomes

↔	No Significant Difference
↕	Inconsistent Evidence
↑	Increased
↓	Decreased

Overview

Table 1 provides an overall summary of the strength of evidence per procedure, comparator, and outcome. ***Only the outcomes that have different strengths of evidence per individual procedures are listed.*** Table 2 provides a detailed summary of the strength and direction of evidence per procedure, comparator, and outcomes.

Table 1. Summary of Procedures, Comparators, and Outcomes by Overall Strength of Evidence

Strength of Evidence			
⊕⊕⊕⊕ High	⊕⊕⊕O Moderate	⊕⊕OO Low	⊕OOO Very Low
Procedure (comparator)			
		Adjustable gastric banding (laparoscopic) • LOS, weight loss, incidence of conversion, complication rate, subgroup findings (BMI >50)	**Adjustable gastric banding** (laparoscopic) • Operative time, costs
		Adnexectomy (laparoscopic)	
			Adrenalectomy (laparoscopic)
		Cardiac procedures (non-robotic) • Operative time, LOS, complication rate, Surgeon experience (mitral valve repair only), costs	**Cardiac procedures** (non-robotic) •
		Cholecystectomy (laparoscopic) • Operative time, LOS, complication rate, costs	**Cholecystectomy** (laparoscopic) • Surgeon experience
	Colorectal surgery (laparoscopic) • EBL, LOS, time to bowel function recovery, time to oral diet	**Colorectal surgery** (laparoscopic) • Operative times, complication rate, costs	
		Colorectal surgery (open) • LOS	

Strength of Evidence			
⊕⊕⊕⊕ High	⊕⊕⊕O Moderate	⊕⊕OO Low	⊕OOO Very Low
Procedure (comparator)			
			Cystectomy (laparoscopic) • Operative time, LOS, blood loss, rate of transfusion, complication rate
	Cystectomy (open) • Operative time, EBL, LOS, complication rate	**Cystectomy** (open) • Costs	
		Fallopian Tube Reanastomosis (open)	
	Fundoplication (open) • LOS, operative time, risk of complications	**Fundoplication** (open) • Costs	
		Gastrectomy (laparoscopic & open)	
		Heller Myotomy (laparoscopic)	
	Hysterectomy (laparoscopic) • Operative duration, LOS, EBL, transfusion risk, complication rate, costs	**Hysterectomy** (laparoscopic) • Cancer recurrence at 2.5 years	**Hysterectomy** (laparoscopic) • Subgroup findings (surgeon experience), pain score, postoperative pain management costs
	Hysterectomy (open) • Operative time, LOS, EBL, transfusion risk, risk of complications, costs	**Hysterectomy** (open) • Subgroup (obese women): operative time, EBL, risk of transfusion, LOS, complications, lymph node yield	

Strength of Evidence			
⊕⊕⊕⊕ High	⊕⊕⊕O Moderate	⊕⊕OO Low	⊕OOO Very Low
Procedure (comparator)			
		Ileovesicostomy (open)	
		Liver resection (laparoscopic)	
		Myomectomy (laparoscopic & open)	
		Nephrectomy (partial, laparoscopic) • LOS, warm ischemic time, EBL, transfusion risk, operative times, complications	**Nephrectomy** (partial, laparoscopic) • Subgroups (surgeon experience): no change in surgical outcomes
			Nephrectomy (radical, laparoscopic) • Operative time, LOS, EBL, transfusion risk, complications, costs
			Nephrectomy (radical, open) • Operative time, LOS, EBL, transfusion risk, complications
			Oropharygeal surgery (open)
		Pancreatectomy (laparoscopic & open)	
	Prostatectomy (laparoscopic & open) • Operative duration, LOS, positive margin rates, EBL, transfusion risk, continence (12 months), complication rates, costs, surgeon experience	**Prostatectomy** (open) • Biochemical recurrence-free survival	

Strength of Evidence			
⊕⊕⊕⊕ High	⊕⊕⊕O Moderate	⊕⊕OO Low	⊕OOO Very Low
Procedure (comparator)			
		Pyeloplasty (laparoscopic)	
		Rectopexy (laparoscopic & open)	
	Roux-en-Y gastric bypass (laparoscopic) • Odds of conversion, operative time	**Roux-en-Y gastric bypass** (laparoscopic) • Complications, operative time, costs **Roux-en-Y gastric bypass** (open) ICU, LOS, complications	
		Sarocolpopexy (laparoscopic & open)	
			Splenectomy (laparoscopic)
		Thymectomy (thoracoscopic & open)	
		Thryoidectomy (open)	
		Thryoidectomy (endoscopic) Operative time, ease of swallowing, cosmetic satisfaction, complications, costs	**Thryoidectomy** (endoscopic) Subgroups (learning curve)
			Trachelectomy (open)
			Vesico-vaginal fistula repair (open)

Notes:

1. LOS = length of stay, EBL = estimated blood loss

2. Only the procedures that had differing strengths of evidence per outcome have specific outcomes listed.

Table 2. Strength of Evidence by Procedure, Comparator, and Outcomes

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Adjustable gastric banding				
Laparoscopic	1 systematic review (1 study) 1 cohort study		*Efficacy* ↔ LOS ↔ Weight loss (1 yr) ↔ Incidence of conversion *Harms* ↔ Complication rate *Subgroups* Morbidly obese (BMI > 50) ↓ Operative time ↔ LOS ↔ Weight loss (1 yr) ↔ Incidence of conversion	*Efficacy* ↕Operative time *Costs* ↑Costs
Adnexectomy				
Laparoscopic	1 systematic review (1 study)		*Efficacy* ↑Surgical duration	
Adrenalectomy				
Laparoscopic	1 cohort study			*Efficacy* ↔ Operative time ↔ Morbidity ↔ Pain ↔ Quality of sleep

[4] No procedure had a high strength of evidence, thus this column is not displayed in this table.

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
				↔ Sleep duration
Cardiac procedures				
Non-robotic[5]	1 systematic review (8 studies) 1 cohort study		*Efficacy* ↑Operative time ↓ LOS ↔ Transfusion rates *Harms* ↕ Complication rate *Subgroups* Surgeon experience ↑Perioperative outcomes (mitral valve repair only) *Costs* ↑ Costs	
Cholecystectomy				
Laparoscopic	1 systematic review (4 studies) 2 cohort studies		*Efficacy* ↑ Operative time ↓ LOS *Harms* ↔ Complication rate	*Subgroups* ↕ Surgeon experience

[5] Includes sternotomy, partial lower sternotomy, mini-thoracotomy, CABG

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
			Costs ↑ Costs	
Colorectal surgery				
Laparoscopic	1 systematic review (7 studies) 1 RCT 6 cohort studies	*Efficacy* ↓EBL ↓LOS ↔ Time to bowel function recovery ↔ Time to oral diet	*Efficacy* ↑ Operative time *Harms* ↔ Complication rate *Subgroups* Experienced vs. less-experienced surgeons ↓ Operative time *Costs* ↑ Costs	
Open	1 cohort study (Park 2011a)		*Efficacy* ↓ LOS ↑ Operative time	

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Cystectomy				
Laparoscopic	1 systematic review (1 studies)			*Efficacy* ↔ Operative time ↓Rate of transfusion ↓EBL ↔LOS *Harms* ↔ Complication rate
Open	1 systematic review (3 studies) 1 RCT 4 cohort studies 1 economic review	*Efficacy* ↑Operative time ↓EBL ↓LOS *Harms* ↔ Complication rate	*Costs* ↓Costs	
Fallopian Tube Reanastomosis				
Open	1 systematic review (2 studies)		*Efficacy* ↔ LOS ↔ Pregnancy rate ↔ Miscarriage rate ↔ Ectopic pregnancy rate ↔ Intrauterine pregnancy rate ↔ EBL ↑Operative time ↑Faster return to work	

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
			Harms ↔ Odds of complications *Costs* ↑ Costs	
Fundoplication				
Laparoscopic	1 systematic review (9 studies)	*Efficacy* ↔ LOS ↔ Operative time *Harms* ↔ Risk of complications	*Costs* ↑Costs	
Gastrectomy				
Laparoscopic	1 systematic review (2 studies) 2 cohort studies		*Efficacy* ↑Faster time to bowel function recovery ↔ EBL ↑Operative time ↔ Lymph node yield ↔ LOS ↔ Time to resume normal diet *Harms* ↔ Complication rate *Costs* ↑ Costs	

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Open	1 systematic review (1 study)		*Efficacy* ↓ EBL ↑Operative time *Harms* ↔ Complication rate	
Heller Myotomy				
Laparoscopic	1 systematic review (3 study)		*Efficacy* ↔ Operative duration *Harms* ↓ Esophageal perforation	
Hysterectomy				
Laparoscopic	1 systematic review (26 studies) 5 cohort studies	*Efficacy* ↔ Operative duration ↓ LOS ↓ EBL ↔ Transfusion risk *Harms* ↓ Complication rate *Costs* ↑ Costs	*Efficacy* ↔ Cancer recurrence at 2.5 years	*Subgroups* ↑ Faster surgical proficiency ↓ EBL among experienced robotic surgeons ↓ Operative time among experienced robotic surgeons ↔ Operative outcomes among experienced

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
				laparoscopic surgeons *Efficacy* ↓ Pain score *Costs* ↑ Postoperative pain management costs
Open	1 systematic review (26 studies) 4 cohort studies	*Efficacy* ↑ Operative time ↓ LOS ↓ EBL ↓ Transfusion risk *Harms* ↓ Complication rate *Costs* ↑ Costs	*Subgroups* Obese women ↑ Operative time ↓ EBL, risk of transfusion ↓ LOS ↓ Complications, including wound complications ↔ Lymph node yield	
Ileovesicostomy				

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Open	1 cohort study			*Efficacy* ↔ Operative time ↔ EBL ↔ LOS *Harms* ↔ Continence ↔ UTIs ↔ Complications *Hospital Costs* ↑ Total hospital *Costs* ↑ *Costs* of operating room supplies ↔ OR fees ↔ Room and board fees ↑ Anesthesia fees ↔ SICU fees
Liver Resection				
Laparoscopic	1 cohort study			*Efficacy* ↔ Operative time ↔ EBL ↔ Tumor recurrence ↔ Overall disease-free survival *Harms* ↕ Complication rate
Lung Surgery				

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Open sternotomy	1 cohort study		*Efficacy* ↔ Operative time ↔ LOS ↓Less post-op pain ↑ QoL scores *Harms* ↔ Complication rate	
Open lobectomy	1 cohort study 1 economic study		*Efficacy* ↓ LOS ↑ Operative time ↓ Lymph node yield *Harms* ↔ Complication rate ↔ Transfusions ↔ 30-day mortality *Subgroups* Experienced vs. less-experienced surgeons ↓ Operative time (still longer than open group) ↓ LOS *Costs* ↕ Costs	
Myomectomy				

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Laparoscopic	1 systematic review (3 study) 1 cohort study 1 economic study		*Efficacy* ↓ EBL ↓ LOS ↔ Operative time *Harms* ↔ Complications *Costs* ↑ Hospital costs	
Open	1 systematic review (3 study 3 cohort studies 2 economic studies		*Efficacy* ↑ Operative time ↓ LOS ↓ EBL *Harms* ↔ Complications *Costs* ↑ Hospital costs	
Nephrectomy				
Partial Laparoscopic	1 systematic review (9 studies) 2 cohort studies		*Efficacy* ↓ LOS ↓ Warm ischemic time ↔ EBL ↔ Transfusion risk ↕ Operative times *Harms*	*Subgroups* *Surgeon experience* ↔ No change in surgical outcomes

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
			↔ Complications	
Radical Laparoscopic	1 systematic review (2 studies)			*Efficacy* ↑ Operative time ↕ LOS ↕ EBL ↕Transfusion risk *Harms* ↔ Complications *Costs* ↑ Hospital costs
Radical Open	1 systematic review (1 study)			*Efficacy* ↑ Operative time ↓ LOS ↓ EBL ↔ Transfusion risk *Harms* ↔ Complications
Oropharyngeal surgery				
Open	1 cohort study			*Efficacy* ↓ LOS ↓ Dependence on gastrostomy tube *Harms* ↔ Complications

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Pancreatectomy				
Laparoscopic	2 cohort studies		*Efficacy* ↕ EBL ↔ LOS ↑ Operative time *Harms* ↔ Complications	
Open	3 cohort studies		*Efficacy* ↓ EBL ↓ LOS ↑ Operative time *Harms* ↔ Complications	
Prostatectomy				
Laparoscopic	1 systematic review (51 studies) 1 cohort study	*Efficacy* ↓Operative duration ↓ LOS ↔ Positive margin rates ↓ EBL ↓ Transfusion risk *Harms* ↔ Complication rate		

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
		Subgroups Experienced vs. less-experienced surgeons ↓Operative time ↓ LOS ↓ Complication rate ↓ Positive margin rate ↔ EBL *Costs* ↑Incremental cost/pt		
Open	1 systematic review (51 studies) 3 cohort studies	*Efficacy* ↓ LOS ↓ EBL ↓ Transfusion risk ↑ Continence (12 months) ↑ Sexual function likelihood (12 months) ↓ Positive margin rates (pT2	*Efficacy* ↔ Biochemical recurrence-free survival	

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
		pts) ↑ Operative time *Harms* ↔ Risk of complications *Subgroups* Experienced vs. less-experienced surgeons ↓Operative time ↓ LOS ↓ Complication rate ↓ Positive margin rate ↔ EBL *Costs* ↑Incremental cost/pt		
Pyeloplasty				
Laparoscopic	1 systematic review (4 studies) 1 cohort study 1 economic study	*Efficacy* ↓Operative time ↔ EBL ↔ LOS ↔ Surgical success rate ↔ Post-op pain ↔ Renal function		

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
			Harms ↔ Complications *Costs* ↑ Costs	
Rectopexy				
Laparoscopic	1 systematic review (1 study) 2 cohort study		*Efficacy* ↑ Operative time ↑ Recurrence *Harms* ↔ Complications *Costs* ↑ Costs	
Open	1 cohort study		*Efficacy* ↑ Operative time ↑ Recurrence *Harms* ↔ Complications	
Roux-en-Y Gastric Bypass				
Laparoscopic	1 systematic review (4 study) 1 RCT 3 cohort studies	*Efficacy* ↑ Odds of conversion ↔ Operative time	*Harms* ↔ Complications *Subgroups* Obese	

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
			↓Operative time (esp. w/ increasing BMI) *Costs* ↑ Costs	
Open	1 cohort		*Efficacy* ↓ ICU ↓ LOS *Harms* ↔ Complications	
Sacrocolpopexy				
Laparoscopic	1 RCT 4 cohort studies 1 economic study		*Efficacy* ↔ Activity limitation ↔ Time until normal activity ↕ Operative time ↕ LOS ↕ EBL ↕ Symptom relief *Harms* ↔ Complications *Costs* ↑ Costs	
Open	1 systematic review (1 study)		*Efficacy* ↕ Operative time	

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
	1 cohort study 1 economic study		↕ LOS ↕ EBL	
Splenectomy				
Laparoscopic	1 cohort study			*Efficacy* ↑ Operative time ↔ LOS ↔ EBL *Harms* ↔ Complications *Costs* ↑ Costs
Thymectomy				
Thoracoscopic	1 cohort study		*Efficacy* ↓ LOS ↔ EBL ↑ Clinical improvement *Harms* ↔ Complications	

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Open	1 cohort study		*Efficacy* ↑ Operative time ↓ LOS ↔ EBL ↑ Clinical improvement *Harms* ↔ Complications	
Thryoidectomy				
Endoscopic	3 cohort studies		*Efficacy* ↕ Operative time ↑ Ease of swallowing ↑ Cosmetic satisfaction *Harms* ↔ Complications *Costs* ↑ Costs	*Subgroup (Surgeon Experience)* ↓ Learning curve
Open	3 cohort studies		*Efficacy* ↑ Operative time *Harms* ↔ Complications	

Procedure		Strength of Evidence[4]		
Procedure Comparator	**Number and type of studies**	⊕⊕⊕O **Moderate**	⊕⊕OO **Low**	⊕OOO **Very Low**
Trachelectomy				
Open	1 cohort study			*Efficacy* ↓ EBL ↓ LOS *Harms* ↔ Complications ↑ Conversion to hysterectomy
Vesico-vaginal Fistula Repair				
Open	1 cohort study			*Efficacy* ↓ EBL ↓ LOS ↔ Operative time ↔ Surgical success rate *Harms* ↔ Complications

Appendix E. EvidenceTables by Procedure

Adjustable Gastric Band

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 1 retrospective cohort N = 20 Muhlmann 2003 N = 20 Robotic = 10 Laparoscopic = 10	Robotic Laparoscopic No follow-up	*Operative time (p=0.04):* Robotic: 137m (range 110-175) Laparoscopic: 97m (range 60-140) *Procedural costs (p < 0.001)* Robotic: $9,505 Laparoscopic: $6,260 *Mean HLOS (NS):* Both groups: 3 days (range 2-4)	Good quality SR Study rated as good quality by SR

Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Edelson 2011	Retrospective cohort	407 robotic, 287 laparoscopic, 120	*Robotic; Laparoscopic* Mean age: 45±11.3 yrs;	Robotic Laparoscopic 1 yr	*Outcome: Robotic; Laparoscopic* Operating time: 91.5±21.1 min; 92.1±30.9 min (NS)	Poor Retrospective study;

			47±11.2 yrs Men/women: 57/230; 31/89 Mean BMI: 45.4±5.5 kg/m^2; 45.1±6.7 kg/m^2 Comorbidities: Similar distribution in each group; NS differences No specific inclusion/exclusion criteria		Operating time in patients with BMI ≥50 kg/m^2: 91.3±19.7 min; 101.3±23.7 min (*P*=0.04) HLOS: 1.3±0.6 days; 1.3±0.6 days (NS) Weight loss at 1 yr: 34.2±0.2%; 34.3±0.2% (NS) Conversion to open procedure: 0%; 0.8% (NS) Postoperative hospitalization: 3.8%; 4.2% (NS) Reoperation: 3.1%; 2.5% (NS)	procedure choice was nonsystematic

Adnexectomy

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Reza 2010	SR/MA 1 prospective cohort n = 176 Robotic = 85 Conventional laparoscopic = 91 Magrina 2009 n = 176	Robotic Laparoscopic No follow-up	*Operative time* Robotic = 12 minutes longer (level of significance not specified) SR reports that all other outcomes reported by Magrina were not statistically different	Good quality SR/MA SR notes that study was not randomized or blinded, but the objective was clearly stated. Other quality indicators were assessed but not described for the individual study.

Adrenalectomy

Individual Studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Brunaud 2004	Chronologically determined controls (controls preceded introduction of robotic equipment)	33 Robotic, 19 Laparoscopic, 14	*Robotic; Laparoscopic* Mean age: 48±2.9 yrs; 44.8±3.3 yrs (NS) BMI: 27.3 kg/m^2; 28.1 kg/m^2 (NS) Tumor type, size, and nonfunctional/ functional ratio were similar Inclusion: Adrenalectomy Exclusion: Open adrenalectomy; Cushing's disease	Robotic Laparoscopic Follow-up: 6 wks	*Outcome: Robotic; Laparoscopic* Operating time: 107±6.6 mins; 86±7.8 mins (NS) Morbidity: 15.8%; 14.2% (NS) Pain, quality of sleep, and sleep duration were similar All SF36 scores were similar, with exception of 1 (role limitations; increased in robotic group, *P*=0.03) No mortalities	Poor Financial disclosure was not reported Historical controls; small sample size; choice of surgical method was made chronologically; surgical data not reported

Atrial Septal Defect Repair

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	SR + MA 1 prospective cohort with retrospective controls and 1 retrospective cohort Total n = 92 Total robotic = 38 Total open = 54 Sternotomy = 16 Mini-thoracotomy = 38 Ak 2007 (n=64) Morgan 2004 (n=28)	Robotic Open procedures (sternotomy, mini-thoracotomy) *Follow-up* Ak 2007: 30 +/- 24.3 months (range 3-105) Morgan 2004: 30 days, robotic group only.	*Operative time (minutes)* Ak 2007 Robotic = 262.6 (60.6) Sternotomy = 147.3 (21.3) P < 0.0001 Morgan 2004 Robotic = 155 (61.5) Mini-thoracotomy = 66.7 (38.2) P < 0.001 *Length of stay (days)* Ak 2007 Robotic = 7.9 (1.9) Sternotomy = 8.2 (2.2) NS Morgan 2004 Robotic: 5.6 (2.6) Mini-thoracotomy = 6.6 (3.7) NS *Transfusion rate* Ak 2007	Good quality SR/MA Both studies rated fair-good by SR Meta-analysis not performed because comparators differed

			Robotic = 1/24 Sternotomy = 0/16 Morgan 2004 NR *Complication rate* Ak 2007 Robotic = 3/24 Sternotomy = 3/16 Morgan 2004 NR	

Coronary Artery Bypass Grafting

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
CADTH 2011	SR + MA 1 prospective cohort (Poston 2008) Total n = 200 Total robotic = 100 Total off-pump CABG = 100	Robotic CABG Off-pump CABG *Follow-up* 1 year	*Operative time (minutes)* Robotic = 348 Non-robotic = 246 P < 0.001 *Length of stay (days)* Robotic = 3.77 (1.51) Non-robotic = 6.38 (2.23) P < 0.001 *Complication rate* Robotic = 24/100 Non-robotic = 57/100 NS	Good quality SR Study rated as good quality by SR

Cholecystectomy

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 1 RCT and 3 cohort studies Total n = 511 Robotic n = 124 Laparoscopic n = 387 Ruurda 2003 (n = 20) Breitenstein 2008 (n = 100) Heemskerk 2005 (n = 24) Giulianotti 2003 (n = 367)	Robotic Laparoscopic Individual study follow-up not described	*Meta-analysis:* *Surgery time* Robotic = 16.96 minutes longer (7.95, 25.96) *LOS* Robotic = 0.73 days shorter (-1.43, -0.03) *Costs* Robotic = $1,692 more ($1,139, $2,245) *Complications* (NS) Robotic = 2.15 greater odds of complications (0.64, 7.25) *Total conversions to open* (NS) Robotic pooled risk difference = -0.01 (-0.04, 0.02) *Incision-closure time* (NS)	Good quality SR SR notes that quality items were assessed for studies but does not specify quality of individual studies; all had clearly described objectives and interventions. SR concludes that robotic cholecystectomy is associated with a shorter hospital stay than laparoscopic procedures, but

				Robotic = 4.14 minutes longer (-6.62, 14.89)	has longer surgery times.
Individual studies (published after review)					
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Jayaraman 2009	Retrospective cohort	36 Robotic, 16 Laparoscopic, 20	*Robotic; Laparoscopic* Mean age: 48.9 yrs; 53.7 yrs Men/women: 7/9; 6/14 Comorbidity: 3; 15 Previous abdominal surgery: 1; 2 Inclusion: Elective cholecystectomy Exclusion: History of extensive upper abdominal surgery	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 91 mins; 48 mins (*P*<0.001) Time to clear operating room: 14 mins; 11 mins (P=0.015) Anesthesia time: 23 mins; 15 mins (NS) No conversions to open procedure Robotic: 1 incisional hernia at 8mm port site; 1 retained biliary stone Laparoscopic: 1 hospitalization for delayed recovery from anesthesia	Poor Retrospective study; control group had more comorbidities than test group; possible difference s in other surgical risks; data represents first use of robotic procedure in institution
Wren 2011	Historic control group	20 Robotic, 10 Laparoscopic, 10	*Robotic; Laparoscopic* Mean age: 58.8±15.9 yrs; 61.8±15.6 yrs (NS) Men/Women:	Robotic Laparoscopic 2-3 wks	*Outcome: Robotic; Laparoscopic* Operating time: 105.3 mins, range 82-139; 106.1 mins, range 70-142 (NS)	Poor Author affiliations with manufacturer; small sample size; historical

			7/10; 7/10 BMI: 28, 28 Inflammatory disease: 60%; 40% Inclusion: >18 yrs of age; appropriate candidate Exclusion: Significant comorbidities or abdominal history		Conversion to open procedure: 10%; 0% Urinary retention: 20%; 20% Major complications: 0%; 10%	controls

Colorectal Surgery (Colorectal Resection, Colectomy, Mesorectal Excision)

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 7 non-randomized controlled studies Total n = 532 Robotic n = 205 Laparoscopic n = 327 Baik 2009 (n = 107) Spinoglio 2008 (n = 211) Rawlings 2007 (n = 57) Pigazzi 2006 (n = 12) Woeste 2005 (n = 27) D'Annibale 2004 (n = 106) Delaney 2003 (n = 12)	Robotic Laparoscopic Individual study follow-up not described	*Meta-analysis:* *Surgery time* Robotic = 39.42 minutes longer (14.99, 63.84) *LOS* Robotic = 0.26 days shorter (-1.55, -1.02) *Costs* Robotic = $792 more ($42, $1,543) *Estimated blood loss* Robotic = 7.04mL fewer (-22.73, 8.66) *Complications* (NS) Robotic = 0.99 odds of complications (0.59, 1.65) *Total conversions to open* (NS)	Good quality SR Studies considered "good quality" by SR SR notes that baseline characteristics not provided in Woeste study; Delaney and Pigazzi had small sample sizes; sections of colon removed were not the same across studies; none of the studies were randomized or blinded.

					Robotic pooled risk difference = -0.01 (-0.01, 0.05) *Lymph nodes* Robotic = 0.20 fewer (-2.40, 2.00) *Distal resection margin* Robotic = 0.38cm (-0.18, 0.95) *Bowel function recovery* Robotic = 0.11 days earlier (-0.46, 0.23) Time to oral diet Robotic = 0.26 days earlier (-0.74, 0.22) *Incision-closure time* (NS) Robotic = 4.14 minutes longer (-6.62, 14.89)	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Patriti 2009	Randomized controlled	66 Robotic, 29	*Robotic; Laparoscopic*	Robotic, 19 mos Laparoscopic,	*Outcome: Robotic; Laparoscopic*	Poor Randomized

	trial	Laparoscopic, 37	Mean age 68±10 yrs; 69±10 yrs Men:Women: 1:1.6; 1:2 BMI: 24, 25 (NS) ASA score and tumor stage: Similar Previous surgery: 18; 11 (*P*<0.01) Tumor distance from anal verge: 5.9±4.2 cm; 11±4.5 (*P*<0.01) Inclusion: Rectal adenocarcinoma Exclusion: None reported	29 mos	Operating time: 202±12 mins; 208±7 mins (NS) Blood loss: 137.4±156 mL; 127±169 mL (NS) Conversion to open procedure: 0; 7 (*P*<0.05) HLOS: 11.9±7.5 days; 9.6±6.9 days (NS) 30-day Morbidity: 30.6%; 18.95 (NS) Long-term morbidity: 26%; 32.8% (NS) Local tumor recurrence rate: 0%; 5.4%	design abandoned after advantage of robotic surgery for low mesorectal dissection was noted, introducing selection bias; differences between groups for previous surgery and tumor distance from anal verge
de Souza 2010	Retrospective cohort	175 Robotic, 40 Laparoscopic, 135	*Robotic; Laparoscopic* Mean age: 71.4±14.1 yrs; 65.3±18.8 yrs Men/Women: 22/18; 62/73 BMI: 27, 27 Cancer: 18; 66 Crohn's: 0; 14 Tumor	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 158.9±36.7 mins; 118.1±38.1 mins (*P*<0.001) Blood loss: 50 mL, range 10-240; 50 mL, range 10-600 (*P*=0.5) Conversion to open procedure: 1; 1	Poor Retrospective study; procedure choice was nonsystematic; fewer patients in robotic group; possible selection bias regarding disease/condition and/or surgical

			characteristics: Similar Inclusion: Right hemicolectomy Exclusion: Emergency procedures; use of hand port; additional procedures		Complications: 8; 28 (NS) HLOS: 5 days, range 3-10; 5 days, range 2-16 (NS) Readmission: 4; 2 (*P*=0.3)	risk
Park 2011a	Retrospective cohort	263 Robotic, 52 Laparoscopic, 123 Open, 88	*Robotic; Laparoscopic: Open* Mean age: 57.3±12.3 yrs; 65.1±10.3 yrs; 62.3±10.4 yrs Men/Women: 28/24; 70/53; 57/31 BMI: 24, 24, 24 ASA score and pre-op serum CEA: Similar Prior abdominal surgery: 17.3%; 20.3%; 14.8% (NS) Distance from anal verge: Similar	Robotic Laparoscopic Open surgery no follow-up	*Outcome: Robotic; Laparoscopic; Open* Operating time: 232.6±52.4 mins; 158.1±49.2 mins; 233.8±59.2 mins (significantly shorter in laparoscopic group, *P*<0.001) Intraoperative transfusion: 1; 1; 0 Pain score: 5.2±1.2; 5.5±1.2; 6.4±1.3 (lower for robotic and laparoscopic groups, *P*<0.001) HLOS: 10.4±4.7 days; 9.8±3.8 days; 12.8±7.1 days (shorter for robotic	Poor Retrospective; procedure choice made by patient and physician; small number of patients in robotic group; robotic group significantly younger than comparators

			Robotic group more likely to have extraperitoneal location; intraperitoneal more likely in other groups (trend; global *P*=0.077) Tumor stage: Similar Inclusion: Tumor located ≤15 cm from anal verge Exclusion: Local tumors; intestinal obstruction or perforation; adjacent organ invasion; metastasis		and laparoscopic groups, *P*<0.001) Perioperative mortality: 0; 0; 1 Complications: 19.2%; 12.2%; 20.5% (NS) No cases converted to open surgery	
Baek 2010	Retrospective cohort (case-matched)	82 Robotic, 41 Laparoscopic, 41	*Robotic; Laparoscopic* Mean age: 63.6 yrs, range 48-87; 63.7 yrs, range 42-88 Men/Women:	Robotic Laparoscopic Follow-up: 30 days	*Outcome: Robotic; Laparoscopic* Operating time: 296 mins (range 150-520); 315 mins (range 174; 584)(NS) Conversion to open	Poor Retrospective; small sample size; baseline differences in patient

			25/16; 25/16 BMI: 25.7 kg/m^2; 26.7 kg/m^2 ASA: similar History of abdominal surgery: 24.4%; 43.9% (*P*=0.06) Chemoradiotherapy: 80.5%; 43.9% (*P*=0.001) Tumor location and stage were similar Inclusion: Rectal surgery; primary rectal cancer Exclusion: Anal cancer; recurrent tumor; benign tumor; concomitant surgery Matching based on gender, age, BMI, and type of procedure		procedure: 7.3%; 22% (NS) Diverting stoma: 94.3%; 40% (P=0) Blood loss: 200 mL; 300 mL HLOS: 6.5 days; 6.6 days Total hospital costs: $83,915; $62,601 (NS) (no detail provided regarding cost calculations) Postoperative complication rates were similar No mortalities	characteristics; possible selection bias

Bianchi 2010	Retrospective cohort	50 Robotic, 25 Laparoscopic, 25	*Robotic; Laparoscopic* Mean age: 69 yrs, range 33-83; 62 yrs, range 42-77 (NS) Men/Women: 18/7; 17/8 BMI: 24.6 kg/m^2 ; 26.5 kg/m^2 (*P*=0.06) Chemoradiotherapy: 52%; 40% (NS) Inclusion: Rectal cancer Exclusion: Emergency cases; stage T4; previous colonic resection	Robotic Laparoscopic Follow-up: mean 10 mos	*Outcome: Robotic; Laparoscopic* Operating time: 240 mins, range 170-420; 237 mins, range 170-545 (NS) Conversion to open procedure: 0; 1 Ileostomy: 40%; 20% (NS) HLOS: 6.5 days; 6 days (NS) Overall complications: 16%; 24% (NS) Reoperation: 1; 2 Pathological findings: similar Survival: 100%, 100% Disease-free survival: 100%, 100%	Poor Retrospective; small sample size; patients assigned to groups based upon availability of robot
Park 2010	Retrospective cohort (case-matched)	123 Robotic, 41 Laparoscopic, 82	Robotic; Laparoscopic Mean age: 61.2±9.4 yrs; 63±9 yrs (NS) Men/Women: 24/17; 49/33 BMI: 23.4 kg/m^2; 23.4 kg/m^2 (NS) Chemoradiation:	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 231.9±61.4 mins; 168.6±49.3 mins (*P*<0.001) HLOS: 9.9 days; 9.4 days (NS) Transfusion: 1; 1 (NS) Specimen extraction via	Poor Retrospective; surgical procedure decided by patient and physician

			34.1%; 20.7% (NS) Previous abdominal surgery: 22%; 17.1% (NS) ASA, CEA, and tumor stage were similar Inclusion: Rectal cancer within 8 cm of anal verge Exclusion: Intestinal obstruction or perforation; adjacent organ invasion; local tumor resectable with transanal access Matching based on age, gender, BMI, date of surgery, ASA score, and tumor stage		natural orifice: 48.8%; 13.4% (*P*<0.001) Postoperative morbidity: 29.3%; 23.2% (NS) No conversions to open procedure Pathological findings: similar No mortalities	

Patel 2011	Nested, matched case-control (robotic surgery patients matched with 2 control groups); matching based on 6 criteria	90 Robotic, 30 Laparoscopic, 30 Hand-assisted laparoscopic, 30	*Robotic; Laparoscopic; Hand-assisted laparoscopic* Mean age: 53.9±11 yrs; 56.3±12.2 yrs; 61.0±13.2 yrs (NS) Men/Women: 19/11; 19/11; 19/11 BMI: 28, 27, 27 Benign vs. malignant diagnosis: Similar ASA score: Similar Prior abdominal or pelvic surgery: 56.7%; 40%; 60% (NS) Distance to anal verge (cm): Similar Inclusion: Surgical procedure of rectum or rectosigmoid	Robotic Laparoscopic Hand-assisted laparoscopic no follow-up	*Outcome: Robotic; Laparoscopic; Hand-assisted laparoscopic* Operating time: 237±56.8 mins; 181.6±52.5 mins; 158.3±51 mins (Robotic significantly longer than comparators) Estimated blood loss: 100.8±48.5 mL; 129.4±108.3 mL; 149.1±122 mL (all analyses NS) Procedural complications: 2 (thermal injury, serosal traction injury of bowel); 0; 0 HLOS: 2.9±1.2 days; 3.9±2.5 days; 3.3±1.1 days (Robotic vs. laparoscopic $P<0.01$) Complications: 13.3%; 10%; 13.3% (all analyses NS) Readmission: 3.3%; 6.7%; 6.7% (all analyses NS)	Poor Small sample size; selection process for 30 out of 70 robotic procedures not reported; data represents early use of robotic procedure in institution

Cystectomy

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Thavaneswaran 2009	SR of 4 non-randomized comparative studies Total n = 173 Total robotic n = 82 Total laparoscopic n = 20 Total open n = 71 Sterrett 2007 (n = 52) Wang 2007 (n = 54) Abraham 2007 (n = 34) Guru 2007 (n = 33)	Robotic cystectomy Open cystectomy or laparoscopic cystectomy No follow-up reported	*Operative time (min)* Study: robotic (range); open (range) Wang 2007: 390 (210-570), 300 (165-540), NS Abraham 2007 NS Guru 2007 NR Sterrett 2007 606 [171], 396 [116], p<0.05 EBL (mL) Study: robotic; open Wang 2007: 400 (100-1200), 750 (250-2500), p=0.002 Abraham 2007: 212 (50-500), laparoscopic: 653 (300-1400) p<0.01 Guru 2007 NR Sterrett 2007: 500 (50-4000), 850 (100-10200), p<0.05	Good quality SR Sterrett 2007, Abraham 2007, Guru 2007: rated as III-3 by SR Wang 2007: rated as III-2 by SR

			HLOS Study: robotic, open Wang 2007: 5 (4-18), 8 (5-28), p=0.007 Abraham 2007: NS Guru 2007: NR Sterrett 2007: 8 (4-23), 10 (2-55), p<0.05 Conversions n/N (%) Study: robotic, open/laparoscopic Wang 2007: 1/33 (3%) Abraham 2007: 0/14 (0%) laparoscopic: 3/20 (15%) Guru 2007: 1/16 (6.3%) Sterrett 2007 NR Transfusions Study: robotic, laparoscopic/open Wang 2007: NR Abraham 2007: 6/14 (42.8%) laparoscopic 14/20 (70%) p<0.01 Guru 2007: NR Sterrett 2007: 10/19 (53%), 23/33 (70%), NS	

			Positive surgical margins: Study: robotic, laparoscopic/open Wang 2007: NS Abraham 2007: 1/14 (7.1%) laparoscopic: 0/20 (0%) Guru 2007: NR Sterrett 2007: NR Complications Study, robotic, open/laparoscopic Wang 2007: 7/33 (21.2%), 5/21 (23.8%), NS Abraham 2007 4/14 (28%), laparoscopic: 14/20 (70%), NS Guru 2007: NR Sterrett 2007 6/19 (32%), open: 10/33 (30%), NS	
Lee 2011a	Economic review 3 cost studies Robotic = 122 Open = 137	Robotic cystectomy Open cystectomy	Clinical outcomes LOS, days Study: robotic, open Smith: 4.7, 5.3, NS Martin: 5.0, 10.0, NS (used for both	Good quality economic review Authors conclude that robotic cystectomy is most

	Smith (n=40) Martin (n=33) Lee (n=186)		modeled and actual costs) Lee: IC: 5.5, 9.0, p<0.05 CCD: 5.8, 8.0, p<0.05 ON: 5.0, 7.8, p<0.05 Operative duration, h Smith: 4.1, 3.8, NS Martin: 4.7, 5.3, NS (used for both modeled and actual costs) Lee: IC: 6.7, 6.0, p<0.05 CCD: 7.5, 8.5, NS ON: 9.0, 7.8, p<0.05 Complication rate, % Smith: 30, 33 Martin: 8, 57 (modeled costs only) Lee: IC: 49.4, 68.6, NS CCD: 50, 65.2, p<0.05 ON: 50, 44.8, NS Direct cost Smith, $16,248, $14,608 (11% increase	cost efficient when costs of complications are considered. Route of urinary diversion may diminish cost performance Cost studies not assigned quality ratings, but limitations in sample size, generalizability (academic institution vs. community setting), selection bias (pts choosing ileal conduit may have fewer complications). 90-d follow-up may have been too short to capture cost of all complications. All studies had

			for robotic) Martin Model: robotic = -15% off of baseline costs for open Actual: open = -16% off of baseline costs for robotic Lee: IC: $19,034, $18,303 (4% increase for robotic) CCD: $20,190, $20,178 (0.06% increase for robotic) ON: $20,862, $19,057 (10% increase for robotic) Indirect costs: Smith: N/A Martin: N/A but considered in analysis Lee: IC: $1624, $7202 (77% decrease for robotic) CCD: $1911, $2520 (24% decrease for robotic) ON: $1823, $1633	two-way sensitivity analyses

					(12% increase for robotic) Total cost Smith: $16,248, $14,608 (11% increase for robotic) Martin: Model: Robotic 15% lower than open baseline cost Actual: Robotic 60% lower than baseline cost Lee: IC: $20,659, $25,505 (19% decrease for robotic) CCD: $22,102, $22,697 (3% decrease for robotic) ON: $22,685, $20,719 (10% increase for robotic)	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Richards 2010	Retrospective cohort	N = 70 Robotic = 35	No statistically significant	Robotic cystectomy	Operative duration (min):	Fair

		Open = 35	differences. Inclusion criteria = patients with clinically localized bladder cancer No exclusion criteria described Men/Women Robotic: 30/5 Open: 25/10 Age: Med (IQR) Robotic: 65 (59-73) Open: 66 (59-73) BMI: Med (IQR) Robotic: 27 (23-31) Open: 26 (24-29) Previous abdominal surgery: Robotic: 15 (43%) Open: 19 (54%) Abdominal radiation:	Open cystectomy 1 month follow-up	Robotic: 530 (458, 593) Open: 420 (368, 492) Diversion (NS): Ileal conduit: Robotic: 30 (86%) Open: 31 (89%) EBL (mL): Med (IQR) Robotic: 350 (250-600) Open: 1000 (500-2000) Transfusion (p<0.01) Robotic: 6 (17%) Open: 25 (71%) Total complications (NS) None: Robotic: 14 (40%) Open: 12 (34%) 1-2: Robotic 14 (40%) Open: 14 (40%) 3+: Robotic: 7 (20%) Open: 9 (25%)	Surgeons chose procedure based on preference Funding source not disclosed Patient characteristics very similar between treatment groups Two surgeons performed both open and robotic; one surgeon performed only robotic All surgeons fellowship-trained urological oncologists with prior open and robotic experience

			Robotic: 0 Open: 1 (3%) Systemic chemotherapy Robotic: 1 (3%) Open: 3 (9%)			
Nepple 2011	Retrospective cohort	N=65 Robotic=36 Open=29	Inclusion criteria: All patients treated with radical cystectomy by a single surgeon from June 2007 to June 2019 for urothelial Ca Exclusion criteria: Patients had relative contraindications to robotic surgery Robotic vs. Open cohorts: male/female%: 86/14 vs. 55/45 (p=0.05); Ave Age: 72/67 (p=0.04; Groups were not	Median follow-up 12.2 months	3 patients converted from robotic to open surgery due to difficult dissection; Mean surgical time was longer in robotic cohort (410 mins vs. 345 mins, p<0.01; Cystectomy pathology was not different for robotic vs. open surgery for stage, margin status, or mean node count. On survival analysis robotic and open cystectomy outcomes were similar with respect to recurrence-free, disease-specific, and overall survival (all log-rank *P* values > 0.05). (K-M estimates	Good

			statistically different in median BMI, Comorbidity index, clinical stage, neoadjuvant chemotherapy exposure;		for 2-year outcomes are reported however median patient follow-up was 12.2 mos)	
Nix 2009	Prospective RCT	N = 41 Robotic = 21 Open = 20	Inclusion criteria: Patients with clinically localized urothelial carcinoma of the bladder Exclusion criteria: (1) Those not surgical candidates for either approach (2) those not allowing randomization (3) those with preconceived preference for a specific surgical modality 14 exclusions	Robotic cystectomy Open cystectomy Follow-up = through hospital discharge	EBL (mL), Mean (Median) ($p<0.01$) Robotic: 258 (200) Open: 575 (600) OR time, Mean (Median) (h) ($p<0.01$) Robotic: 4.20 (4.2) Open: 3.52 (3.4) Time to flatus (d) Robotic: 2.3 (2) Open: (3.2) 3 Median time to BM (d) Robotic: 3.2 (3) Open: 4.3 (4) Median LOS (d) Robotic: 5.1 (4) Open: 6.0 (6)	Fair quality RCT Block randomization performed by desire to educate residents, may have introduced selection bias Varying skill levels of surgeons (residents), no description of learning curve

			resulted No statistically significant demographic differences between treatment groups Age (y) Robotic: 67.4 (33-81) Open: 69.2 (51-80) Male:Female Robotic: 14:7 Open: 17:3 BMI Robotic: 27.5 Open: 28.4 ASA classification Robotic: 2.71 Open: 2.70 Clinical stage: cT1 or lower: Robotic: 6 Open: 5		In-house analgesia (mg morphine equivalent) Robotic: 89.0 (87.5) Open: 147.4 (121.5) Median Clavien units Robotic: 2.3 (2) Open: 2.6 (2)	

			cT2: Robotic: 12 Open: 14 cT3: Robotic: 3 Open: 1 Diversion type: Neobladder: Robotic: 7 Open: 6 Ileal conduit: Robotic: 14 Open: 14			
Ng 2009	Prospective cohort	N = 187 Robotic = 83 Open = 104	Inclusion/exclusion criteria not described No statistically significant baseline demographic differences Male:Female Robotic: 65:18 Open: 73:31 Mean age, SD (y) Robotic: 70.9, 10.8 Open: 67.2, 10.6	Robotic cystectomy Open cystectomy Follow-up = 90 days	Operative time, h (SD) Robotic: 6.25 (1.5) Open: 5.95 (2.2) p=02.9 EBL, mL (SD) Robotic: 460 (299) Open: 1172 (916) p<0.01 PRBC transfused, units (SD) Robotic: 1.42 (1.6) Open: 3.65 (3.9) p<0.01	Good quality Small loss to follow-up (7%) at 90-d in robotic group, unlikely to bias results

			Mean BMI, SD Robotic: 26.3, 3.9 Open: 27.2, 6.0 ASA score 1-2 Robotic: 47 (56.6%) Open: 54 (51.9%) CACI ≤ 2 Robotic: 49 (59.0%) Open: 72 (69.2%) Previous abdominal surgery Robotic: 30 (36.1%) Open: 42 (40.4%) Diversion: Ileal conduit: Robotic: 47 (56.6%) Open: 51 (49.0%) Neobladder: Robotic: 26 (31.3%) Open: 29 (27.9%)		Median LOS, d (range) Robotic: 5.5 (3-28) Open: 8 (3-60) P<0.01 Pts w/major complications, no (%); 30d, 90d Robotic: 8 (9.6), 13 (16.9) Open: 31 (29.8), 32 (30.8) p<0.01, p=0.03 Pts w/complications, no (%); 30d, 90d Robotic: 34 (41.0), 37 (48.1) Open: 61 (58.7), 64 (61.5) p=0.04, p=0.07	

			Indiana pouch: Robotic: 10 (12.0%) Open: 23 (22.1%)			
Sung 2011	Retrospective cohort	N=136 Open n=35 Robotic n=104	Robotic; open; p-value Age, y 62.2 ± 10.5; 65.9 ± 9.4; p=0.05 NS differences between groups in gender, BMI, ASA classification, previous pelvic surgery, intravesical BCG or chemotherapy history, and clinical stage	Robotic Open 90 day follow-up for complications	Robotic; open; p-value *Perioperative outcomes* Mean overall operating time, min 578.2 ± 152.9; 500.6 ± 109.7; p=0.008 Mean overall operating time, ileal conduit, min 482.3 ± 101.2; 494.3 ± 104.3; NS Mean overall operating time, neobladder, min 634.9 ± 151.5; 510.3 ± 102.9; p=0.004 Mean EBL, mL 448.0 ± 231.6; 1063.4 ± 892.7; p<0.001 Mean LN removed 19.1 ± 8.2; 12.9 ± 9.0; p<0.001	Fair quality Non-randomized, retrospective design; small sample size; differences between groups in diversion (neobladder vs. ileal conduit)

					Mean LOS 28.9 ± 11.9; 27.1 ± 13.4; NS NS differences in pathologic stage, organ confined, and LN metastasis *Complications* % Pts w/grade II or greater complications (n) 37.1 (13); 68.2 (71); p=0.001 % Pts w/multiple complications (n) 14.3 (5); 37.5 (39); p=0.011 NS differences in % patients with complications, % with grade I complications, % with major complications, % readmission 4 mortalities within 90	

					days post-op: 3 in open group, one in robotic group *Detailed complications* % wound problem (n) 2.8 (1); 16.3 (17); p=0.043 % urine leakage (n) 8.6 (3); 0.9 (1); p=0.049 % transfusion (n) 11.4 (4); 56.7 (59); p<0.001 NS differences in UTI, ileus, small bowel obstruction, cardiac problem, bleeding, CVA, lymphocele, fistula, death, scrotal edema, duodenal ulcer perforation, vaginal vault prolapsed, peritonitis, C. difficile colitis, ureteral stent fracture, and rectal injury	

					Predictors of grade II or greater complications Type of operation OR = 3.64 (1.64-8.11) for open Sex = 4.06 (1.12-14.11) for female EBL = 2.75 (1.24-6.10) for EBL > 500mL *Learning curve* Operative time decreased with increasing number of surgeries (Pearson correlation r = -0.599, p<0.001) Operative times for last five cases 415.0 ± 89.6 min; 439 ± 63.7 min; p=0.639	

Esophagectomy

Reviews				
Reference	**Study Design and Number of Studies & Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Clark 2009	SR Total n =130 Robotic n = 130 8 non-comparative case series and cohorts Giulianotti (n=5) Bodner (n=4) Ruurda (n=22) Van Hillegesberg (n=21) Kernstein (n=14) Anderson (n=25) Galvani (n=18) Kim (n=21)	Robotic esophagectomy No comparator Operative outcome follow-up = 30-day (n=130) Oncological outcome follow-up = 3-29 months (n=57 cases)	*Robotic only (no comparative studies identified in SR search), Non-weighted means* Operating time (min) = 377 EBL (mL) = 226 ITU stay (days) = 3.72 Hospital stay (days) =15.9 Lymph nodes (n) = 20.7 Pulmonary complications (%) = 25.4 Complications (%) = 31 Perioperative mortality (%) = 2.4	Good quality SR SR notes marked heterogeneity of studies in terms of operative approach and extent of robotic involvement; quality of identified studies described as level 4 evidence based on Oxford Evidence-based Medicine Levels of Evidence

			Disease-specific recurrence rate = 14% (n=8/57) 30-day mortality = 2.4% (3/126) Anastomotic leak rate = 18% (24/130) Conversion to conventional approach = 8 (7%)	

Fallopian tube reanastomosis

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Reza 2010	SR + MA 1 prospective cohort and 1 prospective cohort with retrospective controls Total n = 95 Robotic n = 44 Open n = 51 Rodgers 2007 (n=67) Dharia Patel (n=28)	Robotic fallopian tube reanastomosis Open fallopian tube reanastomosis (laparotomy or mini-laparotomy) Follow-up described as adequate by SR	MA results Robotic surgery vs. open surgery Hospital stay (days) MD = -0.64 (-1.86, 0.58) NS Complications (%) OR = 0.41 (0.08, 2.06) NS Time to return to work (days) MD = -15.97 (-19.55, -12.38) favoring robotic method Pregnancies (%) OR = 0.86 (0.37, 1.99) NS Miscarriages (%) OR = 0.37 (0.11, 1.20)	Good quality SR/MA Summary quality ratings described, but not specified by individual study. SR notes that both studies had clear objectives, were controlled, neither were randomized, but had adequate follow-up (length of follow-up not reported)

			Ectopic pregnancies (%) OR = 1.13 (0.30, 4.33) NS Intrauterine pregnancies (%) OR = 1.99 (0.74, 5.36) NS Duration of surgery (min) MD = 46.85 (34.66, 59.04) favoring open procedures EBL (Rodgers only): Similar between procedures (numbers not reported) Cost: Rodgers: DVS.S associated with significant extra cost of $1446 Dharia Patel: $2000 increase in costs for robotic, + $300/newborn	

Fundoplication

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 4 RCTs and 5 non-randomized controlled studies Total n = 398 Robotic n = 179 Open n = 219 RCTS Muller-Stich (n=40) Draaisma (n=50) Morino (n=50) Nakadi (n=20) Non-randomized studies Hartmannet (n=80) Heemskerk (n=22) Ayav (n=20) Giulianotti (n=76) Melvin (n=40) Nissen fundoplication: Muller-Stich, Draaisma, Morino,	Robotic fundoplication Laparoscopic fundoplication Follow-up cited as adequate but not quantified	Meta-analysis results: Surgery time (min) MD = 20.67 (-9.69, 51.02) NS Incision-closure time (min) MD = -8.40 (-35.91, 19.10) NS LOS (d) MD = -0.08 (-0.41, 0.25) NS Complications RD = -0.02 (-0.12, 0.08) NS Open conversions RD = -0.01 (-0.05, 0.03) NS Total conversions	Good quality SR SR notes that only 1 RCT described randomization and only 1 RCT involved blinding. Non-RCTs did not involve blinding. All but one study compared baseline characteristics. All but two provided statistical comparisons. SR authors

	Nakadi, Heemskerk, Giulianotti, Melvin Dor fundoplication: Hartmannet, Ayav		RD = 0.00 (-0.04, 0.04) NS Costs MD = $1,594 (-$181, $3,374) NS Outcomes reported in SR but not included in meta-analysis: Robotic vs. laparoscopic: Postoperative reflux: NS in 4 studies Dysphagia: NS in 2 studies Quality of life: NS in 3 studies Intra-abdominal pressure, blood pH during follow-up: NSD (2 studies) % requiring daily antisecretory meds after surgery Robotic: 0%	conclude that no differences between procedures in terms of surgery time, length of hospital stay, complications, or conversion to another technique

			Laparoscopic: 30% (p<0.05) (Melvin) NSD (Muller-Stich, Hartmann) Learning curve: Robotic procedure time still longer (131m vs. 97m, p=0.006) after first 10 cases eliminated (Melvin) Surgery time for first 10 cases and last 10 cases NSD (Melvin, Morino); first 21 compared to last 20 significantly different (133m vs. 92m) (Giulianotti)	

Gastrectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 2 non-randomized controlled studies Total n = 87 Robotic n = 36 Laparoscopic n = 51 Song (n=60) Kim (n=27)	Robotic gastrectomy Laparoscopic gastrectomy	**MA results:** LOS (d) -1.38 (-1.84, -0.93) favoring robotic Bowel function recovery (d) -0.21 (-0.42, -0.01) favoring robotic Surgery time (min) 37.60 (1.28, 73.92) favoring laparoscopic EBL (mL) 15.88 (-51.84, 83.59) NS Lymph nodes (number) 0.58 (-4.66, 5.81) NS Complications OR=0.44 (0.07, 2.94) NS	Good quality SR/MA SR notes that neither study was randomized or blinded; baseline differences between treatment groups in both studies: BMI (Kim study), and age and year (Song study)

Clark 2010	SR Identified 1 additional prospective cohort study published after Maeso 2010 Guzman 2009 n = 64 Robotic = 16 Open = 48	Robotic gastrectomy Open gastrectomy 30-day follow up	No statistical tests Operation time (min) Robotic: 399 Open: 298 EBL (mL) Robotic: 200 Open: 353 Complications (%) Robotic: 30% Open: 46% Conversion (n=) Robotic: 0 Open: 0 Hospital stay (days) Robotic: 7 Open: 10 30-day mortality n (%) Robotic: 0 Open: 1 Lymph node (numbers) Robotic: 24 Open: 25	Fair quality SR SR rates quality of identified studies as level 4 evidence based on Oxford Evidence-based Medicine Levels of Evidence

Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Woo 2011	Retrospective Cohort	827 Robotic, 236 Laparoscopic, 591	*Robotic; Laparoscopic* Mean age: 54±12.7 yrs; 58.3±11.6 yrs (*P*<0.001) Men/Women: 136/100; 364/227 BMI: 24, 24 Comorbidities: 42%; 49% (NS) Inclusion: Radical resection for gastric cancer Exclusion: Concomitant procedures	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 219.5±46.8 mins; 170.7±55.8 mins (*P*<0.001) Blood loss: 91.6±152.6 mL; 147.9±269 mL (*P*=0.002) HLOS: 7.7±17.2 days; 7±5.7 days (*P*=0.004) Complications: 11%; 13.7% (NS) Mortality: 0.4%; 0.3% None were converted to open procedure	Poor Retrospective; procedure choice made by patient; patient assumes expense of robotic surgery, which would cause selection bias
Eom 2012	Prospective cohort	N = 92 Robotic n = 30 Laparoscopic n = 62	*Robotic; Laparoscopic* Age (range): 52.8 (28, 74), 57.9 (34, 78), p = 0.04 Male:Female: 21:9, 41:21, NS Mean BMI (range): 24.2 (17, 35), 24.1 (19, 30), NS	Robotic gastrectomy Laparoscopic gastrectomy No follow-up	*Robotic, Laparoscopic* Operative time, min (range): 229.1 (165, 307), 184.4 (125, 272), p<0.001 LN dissection time, min (range): 91.7 (42, 136), 70.2 (23, 118) # retrieved LN: 30.2 (13, 60), 22.4 (10, 67)	Fair quality cohort Insufficient follow-up, baseline differences between treatment groups not

			Tumor size, cm (range): 2.7 (0.4, 9.5), 2.6 (0.5, 5.5) Location: Middle: 17, 30 Lower: 13, 32 NS Histology type: Differentiated: 14, 31 Undifferentiated: 16, 31 NS Lauren classification NS pT (n1, n2, n3, n4): 26, 2, 1, 1; 56, 6, 0, 0, p < 0.001 pN (n0, n1, n2, n3): 24, 3, 1, 2; 52, 6, 3, 1, NS Stage (nI, nII, nIII): 25, 3, 2; 56, 6, 0, p<0.001 Inclusion: diagnosed distal gastric cancer Exclusion criteria		Proximal resection margin: 3.4 (1, 6), 4.3 (1, 10) p = 0.035 DRM: 5.8 (1, 11), 4.7 (1, 13) EBL, mL: 152.8 (10, 500), 88.3 (10, 400), NS Time to diet: 3.4 (3, 6), 3.4 (2, 5) NS Other NS findings: WBC count C-reactive protein No conversions in either group Complications: 4, 4, NS LOS, days: 7.9 (7, 20), 7.8 (5, 17) NS Hospital cost: $11,402 ($7604, $15,292), $6071 ($55, $8995), p<0.001	addressed, may have biased results either direction (robotic group was younger, but had more advanced stage cancer) Patients chose procedure (potential for selection bias, direction unknown but likely favoring robotic procedure)

			not described			

Heller myotomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Maeso 2010	SR + MA 3 non-randomized controlled trials Total n = 252 Huffman (n=61) Iqbal (n=70) Horgan (n=121)	Robotic Heller myotomy Laparoscopic Heller myotomy	Meta-analysis results: Perforations: OR = 0.11 (0.02, 0.56) favoring robotic procedures Surgery time (min) MD = 38.01 (-8.79, 84.81) NS Outcomes not included in meta-analysis: Hospital length of stay Both procedures: 2-3 days LOS longer after robotic in 2 studies (0.2 and 0.7 days), NS EBL (no significant differences) Postoperative difference in pressure	Good quality SR SR notes that Iqbal and Huffman not randomized or blinded and did not compare baseline characteristics of groups. Horgan study did described baseline differences. Affect baseline differences may have had on findings not specified. SR concludes robotic Heller

			exerted by inferior esophageal sphincter = 3mm in favor of robotic procedure (significant, p-value not specified) (Horgan) Postoperative quality of life = better in robotic patients for 2 of 9 categories (Huffman) Learning curve steeper for robotic patients; similar surgery time reached in last 30 robotic patients (Horgan)	myotomy associated with lower risk of perforation and better quality of life.

Hysterectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	N=2,831 *Da Vinci* (n=1,165) Open hysterectomy (n=438) Laparoscopic hysterectomy (n=483) Open radical hysterectomy (n=94) Open type III radical hysterectomy (n=93) Open radical hysterectomy using a modified unilateral Wertheim procedure (n=20) Open total hysterectomy with pelvic lymphadenectomy (n=106) Open hysterectomy and lymphadenectomy (n=191) Laparoscopic total radical hysterectomy (n=8) Laparoscopic total hysterectomy (n=44) Laparoscopic hysterectomy and lymphadenectomy (n=76) Laparotomy (hysterectomy combined with pelvic lymph node dissection, or pelvic paraaortic lymph node dissection) (n=12) Laparoscopic hysterectomy, bilateral salpingo-ppohorectomy, pelvic and periaortic lymph node resection, and cystoscopy (n=20) Laparoscopic staging for endometrial cancer (n=25) Open surgery staging for endometrial cancer (n=56)	Robotic hysterectomy Laparoscopic hysterectomy Follow-up ranged from 14 to 1,382 days	MA Findings for RARH-RATH compared with ORH-OTH *Shorter operative duration* (WMD 63.57 minutes, 95% CI 40.91 to 86.22); *Shorter length of hospital stay* (WMD −2.60 days, 95% CI −2.99 to −2.21); *Reduction in the extent of blood loss* (−222.03 mL, 95% CI −270.84 to −173.22, NS); and *Reduced risk of transfusion* (RR 0.25, 95% CI 0.15 to 0.41, NS).	Good quality SR SR included 5 good quality, 16 fair to good quality, and 5 poor to fair quality studies

	13 Prospective observational studies 13 Retrospective comparison studies		MA Findings for RARH-RATH compared with LRH-LTH: *A meta-analysis was not performed for the "operative duration" outcome due to the high degree of heterogeneity among study findings, which were inconclusive*; *Shorter length of hospital stay* (WMD −0.22 days, 95% CI −0.38 to −0.06); *Reduction in the extent of blood loss* (−60.96 mL, 95% CI −78.37 to −43.54); and *The risk of transfusion exposure was found to be inconclusive* (RR 0.62; 95% CI 0.26 to 1.49) with mixed results reported	

					among the studies.	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Lim 2011	Prospective cohort	244, RHBPPALND, 122 LHBPPALND, 122	Robotic, laparoscopic, p-value Age 62.1 ± 8.4, 61.6 ± 11.8, NS BMI 31.0 ± 8.8, 29.9, ± 7.0, NS	Robotic assisted hysterectomy with lymphadenectomy (RHBPPALND) vs. total laparoscopic hysterectomy with lymphadenectomy (LHBPPALND)	Robotic, laparoscopic, p-value Operating time 147.2 ± 48.2, 186.8 ± 59.8, p<0.001 EBL 81.1 ± 45.9, 207.4 ± 109.4, p<0.001 Lymph node yield 25.1 ± 12.7, 43.1 ± 17.8, p<0.001 Pelvic lymph node yield 19.2 ± 9.0, 24.7 ± 11.9, p<0.001 Para-aortic lymph node yield 5.8 ± 7.8, 18.4 ± 9.7, p<0.001	Fair quality favoring robot

					LOS 1.5 ± 0.9, 3.2 ± 2.3, p<0.001 Measuring operative time with respect to chronological order of each patient who had undergone their respective procedure Case proficiency numbers: RHBPPALND = 24th case LHBPPALND = 49th case The incidence of conversion to open (0.8% vs. 6.5%, respectively; P=0.033), & major complications (4% vs. 12.3%, respectively; P=0.033) was noted to be less for RHBPPALND when compared to	

					LHBPPALND RHBPPALND is associated with shorter hospitalization, less blood loss and less intraoperative and major complications, and lower rate of conversion to open procedure	
Escobar 2011	Matched retrospective cohort	N=90; 30 endometrial CA pts with SPL matched 1:1:1 to 2 cohorts tx'd by traditional or robotic laparoscopy	*Robotic, laparoscopic, P* Age: 59.7, 60.9, NS BMI: 31.4, 31.2, NS Stage IA: 22/30, 8/30 Stage IB: 8/30, 20/30 Stage IC: 0/30, 1/30 Stage 2A: 0/30, 1/30 Grade I: 6/30, 11/30 Grade II: 17/30, 12/30	SPL vs. traditional vs. robotic laparoscopy; f/u NA	*Outcome: Robotic, laparoscopic* OR time, min: 174.0, 219.5 EBL, cc: 75, 100, 0.06 Pelvic LN, % having done: 33.3, 55 Pelvic LN, Median #: 17.0, 13.0 P=0.04 Para-aortic LN, % having done: 33.3, 30 Para-aortic LN, Median #: 3.5, 6.0 Transfusion: 2/30, 0/30 Conversion: 0/30, 1/30	Fair quality Small N, surgeon-skill-dependent outcomes, retrospective design; matched well for most relevant factors

			Grade III: 5/30, 5/30 HTN: 14/30, 13/30 CAD: 2/30, 3/30 DM: 2/30, 3/30 Asthma: 2/30, 2/30		Complications; 1/30 (hypoxia), 2/30 (bowel injury, cystotomy) HLOS (range): 1.4 (1-4), 1.8 (0-7)	
Geppert 2011 (BMI subgroup study)	Retrospective cohort	N=114 Robotic, 50 (25 early; 25 late cases); Open, 64	*Robotic; Open* Mean age: 52.5 yrs (range 35-85); robot grp older ($p<0.05$); median BMI 32.5kg/m^2; robot grp had higher BMI ($p=0.04$) Comorbidities: ASA class, co-morbidities, previous laparotomies (all NS diff.) Inclusion: Indications for hysterectomy were low risk endometrial cancer,	Robotic Open follow-up 12 mos	*Outcome: Robotic; open* Operating time: late robot grp 136 (range 100-183) vs. 110 (49–269) (*P*<0.0004) Blood loss: late robot grp 100 (0–400); 300 (30–2300) (*P*<0.0001) HLOS: 1.6 (1–4)days; 3.8 (1–17)days (*P*<0.0001) Complications: 6/50; 23/64 (*p*=0.003)	Poor quality Open grp had retrospective chart review; robot group had prospective data collection

			bleeding disorders, adenomyosis and myomas Exclusion: 7 (11%) women had uterine size too large for robotic procedure; 10 women (23%) had adnexal mass unsuited for lap. Removal			
Martino 2011	Retrospective cohort	N=215 Robotic hysterectomy: 101 Laparoscopic hysterectomy: 114	Endometrial CA patients; no sig. diff in age, BMI, stage, nodes, comorbidities	Robotic hysterectomy Laparoscopic hysterectomy 24-hr follow-up	*Outcome: Robotic, Laparoscopy; p* **Patient pain score, initial:** 2.1/10, 3.0/10; p = 0.012 Later pain scores: no significant difference **Nursing non-drug pain intervention:** 69/101, 40/114; p<0.01 **Nursing narcotic intervention:** 116/101, 164/114; P=NR **Nursing non-narcotic pain drug:** 46/101, 55/114; p=0.473	Poor quality Risk of selection bias, relies on verbal pain scale, risk of confounding, questionable clinical significance

					Pain med costs, day 1: $12.24, $24.45; p<0.01 **Pain med costs, remainder of stay:** $3.63, $8.17; p<0.01	
Seamon 2009	Retrospective cohort	Robotic Staging: 109 Laparotomy: 191 Matched for surgeon and BMI	Robotic: Age 58y (±10.0) BMI 39.6kg/m^2 (±7.0) ≥3 comorbids: 42.9% Prior surg: 50.5% Laparotomy: Age 62y (±11.5), P=0.03 BMI 39.9kg/m^2 (±6.9) (matched) ≥3 comorbids: 26.3% (P=0.05) Prior Surg: 62.6% (P=0.04)	Robotic staging vs. open laparotomy; non-robotic laparoscopy not considered. Follow-up time not specified; "All postoperative complications were recorded."	*Outcome: Robotic, open* **Adequate staging:** 85%, 91.3%, P=0.16 **Lymphadenectomy:** 87%, 85.2%, P=0.65 **Pelvic LN dissection only:** 27.5%, 28.3%, P=0.98 **Pelvic & aortic LN dissection:** 72.5%, 71.7%, P=0.75 **≥6 Pelvic nodes:** 90.0%, 94.9%, P=0.16 **Pelvic node count:** 18.5±9.5, 18.7±8.7, P=0.91 **≥4 Aortic nodes:** 75.9%, 78.8%, P=0.70 **Aortic node count:** 8.5±5.5, 7.2±4.5, P=0.11 **Rt Aortic node count:**	Poor quality Open pts were older, more prior surgeries; robotic pts had more comorbidities. No intention-to-treat analysis, 17 robotic-to-open conversions and their 29 corresponding matches were dropped from the final analysis

					4.5±2.9, 4.2±2.6, P=0.53 **Lt Aortic node count:** 4.8±3.5, 3.5±3.0, P=0.02 **Total node count:** 24.7±13.2, 23.9±11.8, P=0.45 **Blood loss:** 109mL, 394mL, P<0.001 **Transfusion:** 2%, 9%, OR 0.22 (95%CI 0.05-0.97, P=0.046) **Op time:** 228±43 min, 143±47 min, P<0.001 **Room time:** 284±49 min, 186±51 min, P<0.001) **HLOS:** 1d, 3d, P<0.001 **Non-wound complications:** 11%, 27%, OR 0.29(95%CI 0.13-0.65), P=0.003 **Wound complications:** 2%, 17%, OR 0.10 (95%CI 0.02-0.43, P=0.002)	
Soliman 2011	Prospective cohort	N=95 radical hysterectomy Open = 30	No diff in age, BMI, race, stage, histology	Robotic radical hysterectomy (RRH)	*Outcome: RAH, LRH, RRH; P* **Operative time (min,**	Good quality Strong design, small N, does

		Lap = 31 Robot = 34		Laparoscopic radical hysterectomy (LRH) Open radical hysterectomy (RAH) Follow-up NR	**median):** 265, 338, 328; p=0.002 **EBL (mL, median):** 509.3, 100, 100; p <0.001 **Transfusion, %:** 24, 16, 3; p<0.001 **Conversion, %:** NA, 16, 3; p=0.1 LOS **Post-op infection:** 16/30, 8/31, 3/34; p<0.001 **Negative margins, %:** 96, 97, 97; p=0.99 **Median # pelvic LN:** 19, 14, 17; p=0.26 **Median # lt pelvic LN:** 8.5, 7.0, 7.0; pp=0.96 **Median # rt pelvic LN:** 10.5, 7.0, 9.0; p=0.01 **Median vaginal cuff length, cm:** 1.5, 1.5, 1.5; p=0.10	not allow comparison between surgeons
Subramaniam 2011	Retrospective cohort	N=177; 73 Robotic (11% converted); 104 laparotomy	Obese women w/endometrial CA; mean age 57.0 (SD=11.2) robotic; 61.3 (SD-10.8) laparotomy;	Robotic hysterectomy Open laparotomy hysterectomy	*Outcome: Robotic, Laparotomy; p-value* **% LN removal:** 65.8, 56.7; p=0.227 **# LN:** 8.01, 7.24; p=0.505	Poor quality Retrospective; Selection bias; confounding (age, parity); authors

			p=0.01 Vag Del: 1.79, 2.63; p=0.007	30-day follow-up	**Op time (min):** 246.2, 138.2; p<0.001 **EBL (cc):** 95.9, 408.9; p<0.001 **Hct Chg, %:** 4.67, 4.12; p=0.283 **LOS:** 2.73, 5.07; p<0.001 **Wound comp, %:** 4.1, 20.2; p=0.002 **30-day mort:** 0%, 1%; p=1.00	employed by DaVinci
Tinelli 2011	Prospective cohort	99, TLRH, 76 RRH with pelvic lymph node dissection, 23	Robotic, laparoscopic, p-value Age 43.1 ± 8.9, 41.9 ± 7.1, NS BMI 28 ± 4, 29 ± 3, NS	Laparoscopic radical hysterectomy (TLRH) with lymphadenectomy vs. total robotic radical hysterectomy (RRH) with lymphadenectomy	Blood loss; LOS; OR time; recurrence rate Mean blood loss: RRH = 157 ml (95% CI 50–400); TLRH = 95 ml (95% CI 30–500) (Not Significant) Median length of hospital stay: RRH = 3 days (95% CI 2–7); TLRH = 4 days (95% CI 3–7) (NS) Mean operating time: RRH = 323 min (95%	Good quality

					CI 161–433) (P\0.05); TLRH = 255 min (95% CI 182–415) No significant difference was found between the 2 groups when comparing the recurrence rate	

Ileovesicostomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Vanni 2011	Retrospective cohort	15 Robotic, 8 Open, 7	Robotic; Open Mean age: 53 yrs, range 41-68; 42 yrs, range 23-57 Men/Women: 4/4; 3/4 BMI: 29.2 kg/m^2; 28.4 kg/m^2 Indications for surgery, urodynamics, comorbidities, and medications were similar Inclusion: Incontinent ileovesicostomy; symptomatic neurogenic bladder; unresponsive to medical or conservative	Robotic Open Procedure Median follow-up: Robotic, 15 mos; Open, 13 mos	*Outcome: Robotic; Open* Operating time: 330 mins, range 240-420; 293 mins, range 240-360 (NS) Blood loss: 100 mL, range 10-250; 257 mL, range 100-800 (NS) Transfusion: 0; 1 HLOS: 8 days; 11 days (NS) Incontinence: 2; 4 (NS) Postoperative complications were similar Total hospital costs: $17,344; $12,356 (*P*=0.05) Operating room supplies cost: $3770; $609 (*P*<0.001) Costs for OR fees, room and board, anesthesia, and SICU were similar	Poor Financial disclosure was not reported Retrospective; small sample size; patient chose surgical method; standard deviations of baseline characteristics not reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
			treatments; poor candidates for indwelling catheters Exclusion: Not reported		Costs included direct fixed and variable costs from hospital billing department; professional fees; and robotic maintenance fees ($200,000/year spread across 300 cases) but not purchase price included. Post discharge costs were excluded.	

Liver Resection

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Berber 2010	Retrospective cohort	32 Robotic, 9 Laparoscopic, 23	*Robotic; Laparoscopic* Mean age: 66.6±6.4 yrs; 66.7±9.6 yrs (NS) Men/Women: 7/2; 12/11 Tumor size and type were similar Inclusion: Peripherally-located liver lesions of <5 cm Exclusion: Not reported	Robotic Laparoscopic Mean follow-up: 14 mos	*Outcome: Robotic; Laparoscopic* Operating time: 258.5±27.9 mins; 233.6±16.4 mins (NS) Blood loss: 136±61 mL; 155±54 mL (NS) Conversion to open procedure: 1; 0 Complications: 11%; 17% Tumor recurrence: 2; 6 (NS) Overall survival and disease-free survival were similar	Poor Two authors are consultants for robot manufacturer Retrospective; small sample size; surgical method selected by robot availability and preference of surgeon; statistical significance of data not always reported

Lung Surgery, Thoracoscopic Resection

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Veronesi 2010	Retrospective cohort (with matched controls)	108 Robotic, 54 Open, 54	*Robotic; Open* Mean age: <55 yrs: 8; 11 55-59 yrs: 12; 13 60-64 yrs: 19; 14 >65 yrs: 15; 16 (all analyses NS) Men/Women: 38/16; 34/20 (NS) Tumor stage, lymph node status, ASA score, disease stage, and BMI were similar Inclusion: Suspected or proven stage I or II lung cancer; lesion <5 cm; <75 yrs of age;	Robotic Open 30 days	7 pts converted to open lobectomy Postoperative complications and transfusions were similar No mortalities at 30-days Outcomes analyzed according to 3 chronologically defined tertiles of robotic procedures (earliest 18, next 18, last 18) *Outcome: Robotic tertile 1; 2; 3; Open* Operating time: 260 mins; 213 mins; 235 mins; 154 mins (tertile 1 vs. tertile 2+3, *P*=0.02; tertile 2+3 vs. open, *P*<0.001) HLOS: 6 days; 5 days; 4 days; 6 days (tertile 1 vs.	Fair Financial disclosure not reported Retrospective; surgical method determined by surgeon's choice, robot availability, and location of lesion; robotic operative data presented as tertiles and overall data was not directly compared with control group

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			normal respiratory function Exclusion: Prior thoracic surgery; neoadjuvant treatment Matching conducted using propensity score based upon 10 criteria		tertile 2+3, *P*=0.002; tertile 2+3 vs. open, *P*=0.002) Number of lymph nodes removed at first level were similar, however, number at second level was greater for open group (*P*=0.04) Robotic procedure cost 2000 Euros more than the open procedure (no details provided).	
Balduyck 2011	Retrospective cohort	36 Robotic, 14 Open, 22	*Robotic; Open* Mean age: 49 yrs, range 18-63; 56 yrs, range 23-84 (NS) Men/Women: 4/10; 12/10 Inclusion: Resectable anterior	Robotic Open median sternotomy 12 mos	*Outcome: Robotic; Open* Operating time: 242.2±66.5 mins; 243.8±55.5 mins (NS) HLOS: 9.6 days; 11.8 days (NS) Mass diameter: 6.37±3.97 cm; 10.32±3.78 cm (*P*=0.005) Mean follow-up: Robotic, 34.2 mos; Open,	Poor Financial disclosure not reported Retrospective; small sample size; limited patient characteristics;

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			mediastinal mass Exclusion for robotic: Mass >4 cm; local invasion in surrounding great vessels; inability to sustain single-lung ventilation Patients with masses >4 cm were treated by open sternotomy		50.1 mos (*P*<0.003) 1 pt converted to open sternotomy Perioperative and postoperative complications and pathological diagnoses were similar QoL questionnaire revealed that open group had physical, role, and social functioning impairment, and fatigue at 1 mo, unlike robotic group. Open group still had thoracic pain at 3 mos, unlike robotic group. Robotic group had shoulder dysfunction at 3 mos, but not at 1 mo.	patients in open sternotomy group had larger masses; entry criteria varied for different treatment groups; QoL scores not compared between groups
Park 2008	Cost analysis	N=281 Robotic n = 12 Open lobectomy n = 269	Not described.	Robotic lobectomy Open lobectomy No follow-up	Robotic, open Total relative cost: $4,380, $8,368 Robotic group had add'l	Poor quality cost analysis No description of patient

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
					$730 in direct costs from disposable instrument costs	characteristics; no sensitivity analysis; most patients undergoing robotic procedure also underwent concurrent procedure; no assumptions stated

Mitral Valve Surgery

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
CADTH 2011	N=761 Folliguet (2006) n=50 *Da Vinci* (n=25) Sternotomy mitral valve repair (n=25) Prospective observational (robotic) compared with historical cohort Tabata (2006) n=128 *Da Vinci* (n=5) Minimally invasive mitral valve repair with direct vision	Robotic mitral valve repair Sternotomy Follow-up 24 months Sternotomy Follow-up 45 ± 10 months for *Da Vinci*; 54±32 months for	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 241±53.3 vs. 188±24.3 (P=0.002) • *LOS (days)* = 7±3.22 vs. 9±4.5 (NS) • *Transfusion Rate* = 2/25 vs. 4/25 (NS) • *Complication Rate* = 8/25 vs. 5/25 Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 213±52 vs. 125±39 • *LOS (days)* = 6.6±5.3	Good quality SR SR included 4 fair to good quality, and 1 poor to fair quality studies

	for MR (n=123) Retrospective comparison	comparator	vs. 7.9±6.3 (P not reported) • *Transfusion Rate* = NR • *Complication Rate* = NR	
	Woo (2006) n=64 *Da Vinci* (n=25) Sternotomy (n=39) Retrospective comparison	Sternotomy Length of follow-up not reported	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 2391±12 vs. 162±10 (P=0.001) • *LOS (days)* = 7.10±0.9 vs. 10.6±2.1 (P=0.039) • *Transfusion Rate* = NR • *Complication Rate* = NR	
	Mihalijevic (2011) n=375 *Da Vinci* (n=261) Complete sternotomy (n=114) Retrospective Comparison	Sternotomy Follow-up ≥ 30 days	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 387 vs. 278 (P=0.001) • *LOS (days)* =	

			4.2±1.93 vs. 5.2±2.6 (P<0.001) • *Transfusion Rate* = NR • *Complication Rate* = 54/106 vs. 71/106	
	Kam (2010) n=144 *Da Vinci* (n=104) Conventional mitral valve repair (n=40) Retrospective comparison	Sternotomy Length of follow-up not reported	Findings for RA MVR compared with sternotomy • *Operative time (minutes)* = 238.6 vs. 162 (mean relative difference 1.18; 95% CI 1.11, 1.27; P<0.001) • *LOS (days)* = 6.5±2.99 vs. 8.8±4.4 (mean relative difference 0.74; 95% CI 0.68, 0.80; P<0.001P=0.039) • *Transfusion Rate* = NR *Complication Rate* = NR	

Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Suri 2011	Retrospective observational comparative study, propensity matched	190, Robot, 95, Open, 95	Robotic, open, p-value Age 54.88 ± 11.04, 55.69 ± 14.09, NS BMI 26.83 ± 3.57, 26.95 ± 4.41, NS Other NS differences: Creatinine, ejection fraction, cerebrovascular disease, chronic lung disease, congestive heart failure, coronary disease, diabetes, dyslipidemia, hypertension, gender, myocardial infarction, NYHA 1 and 2,	Mitral valve repair robot vs. open	Median crossclamp & bypass times were longer in robotic group but decreased significantly over time (P<.001). There were no conversions to open sternotomy, repair rate & early survival were 100%, dismissal mitral regurgitation grade was similar (P=1.00), & all pts in the robotic group had mild or less mitral regurgitation at 1 month after repair. There were no differences in adverse events (5% open vs. 4% robotic, P=1.00). Pts in the robotic group had shorter postoperative ventilation time, intensive care unit	Good quality The incidence of early major AEs after open & robotic degenerative MV repair are similarly low and less than recently reported in the EVEREST II trial, thereby establishing an appropriate benchmark against which future nonsurgical therapies should be evaluated.

			preoperative atrial fibrillation, Charlson score		stay, & hospital stay.	

Myomectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Reza 2010	SR/MA Three prospective cohorts, one used historical controls N = 189 Robotic n = 84 Laparoscopic n = 76 Laparotomy n = 29 Advincula 2007 (n=58) Bedient 2009 (n=81) Nezhat 2009 (n=50)	Robotic myomectomy Laparoscopic myomectomy Open myomectomy	Meta-analysis results: Robotic vs. laparoscopic surgery: (95% CI) Blood loss (mL) MD = -72.36 (-133.22, -11.50) favoring robotic procedure Duration of surgery (min) MD = 0.18 (-54.42, 54.79) NS Outcomes not included in meta-analysis but reported in SR: Robotic vs. open: Cost: Robotic procedure associated with increased costs of $18,000 (p<0.001)	Good quality SR Summary quality ratings described, but not specified by individual study. SR notes that all studies had clear objectives, were controlled, were not randomized, but had adequate follow-up (length of follow-up not reported)

				Duration of surgery (min) Robotic = 80 minutes longer (p<0.001) Hospital stay = 2 days shorter in robotic group (p = 0.001) Blood loss was reduced by 170 ml (*P* = 0.011).	
Individual studies (published after review)					
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Ascher 2010	Retrospective review and historical control group	125 Robotic: 75 Open: 50	Robotic; Open Mean age: 36.5±7.2; 37.2±5.4 (NS) BMI: 21.7 kg/m^2; 20.1 kg/m^2 (NS) Inclusion: Uterus ≤20 wks in size; ≤3 myomas Exclusion: Previous uterine surgery	Robotic Open No follow-up	*Outcome: Robotic; Open* *(95% CI)* Operating time: 192.3 mins (58.6, 326.0); 138.6 mins (30.3, 246.8)(*P*=0.01) Blood loss: 226.3 mL (-271.7, 724.4); 459 mL (-405.5, 1323.5)(*P*=0.009) HLOS: 0.51 days (-0.8, 1.8); 3.3 days (1.1,	Poor Selection bias, while suspected, could not be assessed. Retrospective; historical control group; patients in robotic grp were

					5.4)(*P*=0) # of Fibroids: 2.4 (-2.1, 6.8); 1.7 (0.1, 3.2)(NS) Febrile morbidity: 1.3%; 38% (*P*=0) Operative and postoperative complications were similar	outpatients so they self monitored body temperature, therefore fever may not have been detected or reported Authors noted that uterine suture repair which is critical to avoid future pregnancy-related uterine rupture is difficult to perform laparoscopically; the robotic approach is more comparable to an open approach in addressing this concern; furthermore, the inability to

						palpate for small myomas is not possible with the robotic approach as it is with the open surgery which potential could lead to different long-term pathologic outcomes.
Advincula 2007	Nested case-control (derived from a retrospective chart review); Controls were open procedures performed during same time frame, matched to cases of robotic surgery according to	58 Robotic, 29 Open, 29	*Robotic; Laparotomy* Mean age: 37 yrs; 35 yrs Men/women: 7/9; 6/14 BMI: 25, 28 Leiomyoma weight (g): 228, 224 *Inclusion criteria for robotic procedure:* Symptomatic leiomyomata thought to be approachable with conventional	Robotic Laparotomy (open) No follow-up No comparison with laparoscopy because prior to introduction of robotic system, primary author preferred to avoid laparoscopy due to dissatisfaction with	*Outcomes: Robotic; Laparotomy* Operative time (min) (mean and 95% CI) : 231.38 (199.01-263.75); 154.41 (138.00-170.82) (*P*<0.0001) Blood loss (mL) (mean and 90% CR): 195.69 (50.00-700.00); 364.66 (75.00-1550.00) (*P*=0.0112) HLOS: (day and 90% CR): 1.48 (1.00-3.00); 3.62 (3.00-8.00) (*P*<0.0001)	Good quality cost analysis but poor-fair operative outcomes data Single surgeon performed robotic procedures but 6 surgeons performed control procedures; control procedures not necessarily eligible for

	weight of leiomyomata (most important) and patients' BMI and age.		laparoscopic myomectomy because of size, #, location, or combination.	instrumentation	(CR=central range for non-normally distributed data) Primarily a U.S. hospital perspective; direct variable costs, including professional costs. Costs derived from internal hospital systems, collected May 2000 – June 2004 and inflation-adjusted to June 2004. Charges included operating department, anesthesia, nursing, laboratory, pharmacy, and recovery department. Remaining cost of hospital stay and cost of follow-up care excluded. Intent-to-treat analysis (conversions counted in originally planned surgical group). *Charges (professional plus hospital, equated*	laparoscopic myomectomy at other institutions; robotic group had more numerous symptoms; results may not generalize to institutions using a donated robotic system; omission of postsurgical costs of the hospital stay limits usefulness even from a hospital perspective; costs were apparently adjusted according to general rather than medical inflation index

					with hospital costs): Robotic; Open $36,031 (90% CR 28,528-50,618); $18,065 (90% CR 12,737-31,647) *Reimbursement (professional plus hospital): Robotic; Open* $15,444 (90% CR 1134-3,753); $8857 (90% CR 4766-12,258) Total hospital and professional components of charges and reimbursements were greater for robotic procedures, but robotic-open difference in professional reimbursement was NS. The biggest single difference was in a component of hospital charges, operating department charges ($16,916 robotic vs. $2165 open); most	

					other hospital charges were greater for open procedures). 5-year depreciation costs accounted for $10,569 of operating room costs for each robotic procedure.	
Barakat 2011	Retrospective cohort assembled from single clinic	N=575 Open n=393 Laparoscopic n=93 Robotic n=89	*Robotic; laparoscopic; open* Age (IQR) 37 (33-40); 38 (35-44); 37 (33-41), p=0.053 Weight (IQR) 68.04 (57.65, 82.56); 64.86 (59.1, 76.66); 75.57 (62.85, 90.72); p<0.001 BMI (IQR) 25.15 (22.14, 29.44); 24.10 (22.00, 28.01); 27.61 (23.43, 32.81) Previous myomectomy, operative laparoscopy, tubal	Open myomectomy; laparoscopic myomectomy; robotic-assisted myomectomy No follow-up	*Robotic; laparoscopic; open* Surgical time, min (IQR) 181 (151, 265); 155 (98, 200); 126 (95, 177), p=0.003 abdominal vs. robotic; p=0.083 laparoscopic vs. robotic Blood loss, mL (IQR) 100 (50, 212.50); 150 (100, 200); 200 (100, 437.50), p<0.001 abdominal vs. robotic; p=.818 robotic vs. laparoscopic Hemoglobin drop, g/dL (IQR) 1.30 (0.80, 2.28); 1.55 (1.20, 2.40); 2.00 (1.40, 2.90), p<0.001 abdominal vs. robotic; p=0.431 laparoscopic	Poor quality Not randomized; no follow-up; unclear whether "experienced surgeons" had experience specifically with robotic surgery; significant differences between groups at baseline (robotic and laparoscopic groups had lower BMI than open group; robotic group was less likely to

			ligation or cesarean section significantly different between groups (fewer in robotic group had previous surgery) Height, parity, other previous abdominal surgery not statistically significant different between groups Inclusion/exclusion criteria not described		vs. robotic Hospital stay, days (IQR) 1.0 (1.0, 1.0); 1.0 (0.0, 1.0); 3.0 (2.0, 3.0), p<0.001 abdominal vs. robotic; p=0.506 laparoscopic vs. robotic Blood transfusion, frequency 7.41%, 0.00%, 92.6%; p=0.008 Postoperative complications, frequency 0.00%, 66.67%, 33.33%, p=0.13	have had prior abdominal surgery)
Behera 2011	Cost-minimization analysis		*Parameter estimates, baseline, range: open; laparoscopic; robotic* Operative time, min: 154 (85-154); 264 (79-264); 234 (152-234)	Open myomectomy; laparoscopic myomectomy, robotic myomectomy	*Open, laparoscopic, robotic* *Existing robot model* $4937; $6199; $7280 Open procedure remained least expensive after sensitivity analysis, unless: Length of hospital stay for open surgery was	Fair quality Underlying evidence limited on long term outcomes; outcomes related to quality of life were not incorporated or

			Conversion risk, % N/A; 8.8 (0-13.3); 6.9 (0-6.9) Transfusion risk, % 6.1 (6.1-6.9); 0 (0-0); 0 (0-0) Length of stay, days 2 (2-4.1); 1.6 (0.6-2.2); 1.5 (0.2-1.5) *Cost estimates* Preoperative costs 94; 94; 94 Intraoperative costs (range) 1068 (1068-4902); 1047 (1047-5207); 1047 (1047-5207) Anesthesia setup fee 339, 339, 339 Disposable instrument costs		greater than 4.3 days (laparoscopic became least expensive); or Surgeon's fee for open surgery was greater than $3473 (laparoscopic became least expensive; robotic was less expensive than open, but more than laparoscopic) Cost of robotic procedure consistently higher than laparoscopic; robotic only less expensive if disposable instrument costs were less than $1400 and laparoscopic disposable costs remained $1151 *Robot purchase model* Robotic cost increased incrementally by $2814, $1939, and $1090 when purchase of robot is amortized over 12, 18 and 32	valued; only direct costs were assessed

			200 (0-1000); 1151 (500-2000); 2511 (1000-4000) Early conversion costs N/A; 712, 1154 Postoperative anesthesia care unit cost (range) 400 (101-808); 214 (76-374); 214 (76-374) Robot acquisition and maintenance costs, monthly costs, amortized 7 years for 5% at base case N/A; N/A; 34893 (33036-41172)		months, respectively	
Nash 2011	Retrospective cohort at single institution	N=133 Robotic n=27 Open n=106 Propensity matched comparison	*Open; robotic; OR (95% CI)* *BMI (SD)* 26.5 (6.16); 24.97 (4.81); 0.93 (0.83-1.03) Age (SD)	Open myomectomy Robotic myomectomy	*Open, robotic, p-value* *Results stratified by specimen size: smallest, intermediate, largest* Mean total hospital charges: $26,865, $27,645,	Fair quality Small sample size, may be underpowered to detect smaller

		Open n=54 Robotic n=27	35.78 (5.47); 38.26 (6.30); 1.10 (0.99-1.22) Uterine size (SD) 16.06 (4.80); 12.74 (4.55); 0.76 (0.65-0.90) Medicaid 7.7%; 3.7%; 0.17 (0.01-2.74) White/other 68.9%; 59.3%; reference African American 23.6%; 37.0%; 3.02 (0.97-9.38) Hispanic 7.5%; 3.7%; 0.31 (0.02-5.26) Indication pain 56.6%; 77.8%; 2.03 (0.65-6.37) Indication bleeding 73.6%; 51.9%; 0.26 (0.08-0.81) Indication gastrointestinal 10.4%; 29.6%; 2.01 (0.55-7.39)		$34,892; $43,465, $48,549, $52,478, p<0.0001 Mean operating room charges: $16,790, $17,313, $22,173; $34,796, $39,981, $41,517, p<0.0001 Mean total operating room minutes (SD): 106.15 (36.84), 117.82 (51.77), 157.86 (56.93); 183.90 (70.54), 239.33 (76.41), 280.40 (121.66), p<0.0001 Mean length of stay (SD) 2.31 (0.63), 2.38 (0.70), 2.65 (1.17); 0.50 (0.71), 0.67 (0.65), 1.20 (1.64), p=0.007 Median (IQR) grams of specimen removed per operating room hour 57.46 (140.46), 129.47	differences; selection bias well accounted for using propensity score matching; cost outcomes include only direct costs

			Inclusion/exclusion criteria Propensity score modeling uses to exclude pts who underwent open procedure who would have been unlikely to undergo robotic		(79.49), 208.53 (273.31); 19.61 (24.08), 39.9 (57.05), 102.36 (90.58), p<0.0001 Percent IV hydromorphone 84.6%, 80.0%, 81.4%; 50.0%, 66.7%, 40.0%, p=0.01 NS differences in estimated blood loss, post op hemoglobin, maximum pain score, % any complications *Propensity score 2-1 matched comparison* Efficiency outcomes Mean (SD) total hospital charges $26,720 (7,830); $47,478 (10,883), p<0.0001 Mean (SD) operating room charges $17,037 ($4,516); $37,901 ($10,324),	

					p<0.0001 Mean (SD) total operating room minutes 114.54 (39.06); 226.41 (88.33), p<0.0001 Median (IQR) grams of specimen removed per operating room hour 139.66 (115.98); 38.56 (75.90), p<0.0001 Mean (SD) length of stay 2.3 (0.662); 0.70 (0.91), p=0.001 Clinical outcomes NS (estimated blood loss, post op hemoglobin, max pain score, any complications)	

Nephrectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	SR + MA N=737 *Da Vinci* (N=343) Laparoscopic partial nephrectomy (N=130) Laparoscopic partial nephrectomy (N=172) Laparoscopic partial/wedge nephrectomy (N=11) Laparoscopic tranperitoneal partial nephrectomy (N=15) Laparoscopic radical nephrectomy (N=15) Laparoscopic nephrectomy with hand assistance (N=21) Laparoscopic nephrectomy (N=12) Open radical nephrectomy (N=18) 4 Prospective observational studies 6 Retrospective comparison studies	Laparoscopic or open surgery Follow-up ranged from 4 months to 4 years	MA Findings for RAPN compared with LRN: *For operative duration*, there is a high degree of heterogeneity and mixed results among studies, and a meta-analysis was not performed ; Shorter length of hospital stay (WMD −0.25 days, 95% CI −0.47 days to −0.03 days); *The extent of blood loss in this comparison was not statistically significant* (−17.44 mL, 95% CI −53.63 to 18.75 mL);	Good quality SR SR included 1 good quality, 8 fair to good quality, and 1 poor to fair quality studies

			Risk of transfusion was found to be inconclusive in this comparison (RR 0.85, 95% CI 0.24 to 3.09, NS); and *Reduced warm ischemic time* (WMD −4.18 minutes, 95% CI −8.17 to −0.18 minutes). MA Findings for Radial Nephrectomy compared with Laparoscopic Radical Nephrectomy and Open Radical Nephrectomy: *Longer operative times were statistically significant in both studies*; and *LOS, blood loss, and risk of transfusion were inconclusive* between the 2 studies.	

Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Hillyer 2011	Comparative retrospective review	26 Bilateral RPN, 9 Sequential bilateral LPN, 17	Men (%), black race (%), age, BMI, preoperative estimated glomerular filtration rate, average ASA score, tumor location all NS differences between groups Robotic, laparoscopic, p-value Tumor size 2.85, 2.7, p=0.03 Pattern (exophytic, mesophytic or endophytic) More endophytic in robotic group, p = 0.008 Position, fewer	Robot (RPN) vs. laparoscopic partial nephrectomy (LPN) bilaterally	A total of 18 procedures were performed in the RPN group and 32 in the LPN group. The median warm ischemia time was shorter in the RPN group than in the LPN group (19 vs. 37 minutes, respectively; *P*=0.059). The median tumor size was 2.85 and 2.7 cm in the RPN and LPN group, respectively (*P*=0.03). The final median postoperative glomerular filtration rate was 68.7mL/min/1.73 m2 (interquartile range 14-73) and 26.9 mL/min/1.73 m2 (interquartile range 20-70) in the RPN and	Good quality To our knowledge, this represents the first study to offer such a comparative analysis of a specific subset of patients with bilateral synchronous tumors.

			lateral in robotic group, p=0.02 Sinus fat invasion more common in robotic group, p=0.006		LPN groups, respectively (*P*=0.004). No difference was found in the complications in the RPN group (n=2) compared with the LPN group (n= 4).	
Pierorazio 2011	Retrospective cohort design	N=150 Robotic=48 Laparoscopic=102	Baseline characteristics robot vs. lap: Gender mostly male (NS); Age median 62 vs. 56 (p=.006); BMI 28.2 vs. 30.3 (p=.053); Tumor characteristics similar (NS); Inclusion criteria: single surgeon since 2006 cases of renal mass solid tumor undergoing either type surgery to present (2011) Exclusion criteria: unclear	Laparoscopic partial nephrectomies (LPN) and Robot-assisted partial nephrectomies (RAPN); cohorts were divided groups of 25 consecutive patients in each group to study the learning curve effect on surgical outcomes; Follow-up: to discharge in most but 57 patients are reported for GRF with a median 7 months,	Perioperative outcomes: LPN vs. RAPN Mean operative times (min): 193 (100-420); vs. 152 (108-265) p<.001; Warm ischemic time (min): 18 (8-65) vs. 14 (8-30) p<.001; Mean EBL (mL): 245 (50-1700) vs. 122 (0-500) p=.001; Transfusions (%): 4.9 vs. (NS); LOS (days): 2 vs. 2 (NS)	Good Very experienced laparoscopic surgeon was sole surgeon in both treatment arms of study. Results of learning curves may not be generalizable to other surgeons.

				range 1-43 months…(unclear which group or groups this represents)		

Oropharnygeal Surgery

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Dean 2010	Retrospective cohort	21 Robotic salvage, 7 Open salvage, 14 (an additional 15 patients were reported to have undergone robotic resection for primary neoplasms without a comparison group)	*Robotic; Open* Mean age: 67.7 yrs ±NR; 59.0 yrs ±NR (P=NR) Men/Women: 6/1; 12/2 (NR) Primary tumor subsite: Base of tongue (5), Soft palate/Pharyngeal wall (1); Base of tongue (5), Tonsil (5), Soft palate (4) T stage: T1 4/3; T2 3/11 (NR) Previous head/neck therapy: Surgery 0/1; Radiation 2/6; Chemoradiotherapy 2/4; Surgery + radiation 1/3; Surgery + chemoradiotherapy 2/0 (NR)	Robotic or Open Salvage; Follow-up 6 months	*Outcome: Robotic; Open* HLOS: 5.0; 8.2 (NS) Gastrostomy tube dependent at 6 months 0%/43% (NR) Complications: 0/2 (NS)	Poor Retrospective; small sample size; baseline group differences only statistically analyzed between all 3 groups; most outcomes reported in narrative form; comparative groups drawn from 2 time epochs; patient's selected their treatment modality

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
			Inclusion: Recurrent T1 or T2 oropharyngeal neoplasms; Exclusion: T3 or T4 disease			

Pancreatectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Kang 2011a	Retrospective cohort	45 Robotic, 20 Laparoscopic, 25	*Robotic; Laparoscopic* Mean age: 44.5±15.9 yrs; 56.5±13.9 yrs (P=0.02) Men/Women: 8/12; 11/14 (NS) BMI: 24.2 kg/m^2; 23.4 kg/m^2 (NS) Inclusion: Distal pancreatectomy for benign and borderline malignant tumors; intent to preserve spleen Exclusion: Central pancreatectomy	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 348.7±121.8 mins; 258.2±118.6 mins (P=0.02) Blood loss: 372.0±341.5 mL; 420.2±445.5 mL (NS) Transfusion: 4; 4 (NS) HLOS: 7.1±2.2; 7.3±3 (NS) Complications: 2; 4 (NS) Failed spleen preservation: 1; 9 (*P*=0.03) Total cost (converted from Korean won, July 2010 rate): $8304.8±870.0; $3861.7±627.5 (*P*<0.001) Operation cost: $5752.6±380.5; $2222.1±627.5 (*P*<0.001) (no cost details were provided)	Poor Retrospective; small sample size; age difference favoring robotic group; patients chose surgical method
Zhou 2011	Retrospective cohort	16 Robotic, 8	*Robotic; Open* Mean age:	Robotic Open	*Outcome: Robotic; Open* Operating time:	Poor

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
		Open, 8	64.4±9.1 yrs; 59.4±9.4 yrs (NS) Men/Women: 5/3; 4/4 (NS) Levels of bilirubin, CA19-9, and CEA were similar Inclusion: Pancreatoduoden-ectomy Exclusion: None reported	No follow-up	718.8±186.7 mins; 420.0±127.2 mins (*P*=0.011) Blood loss: 153.75±43.4 mL; 210±53.2 mL (*P*=0.045) HLOS: 16.4±7.1 days; 24.3±7.1 days (*P*=0.04) Reoperation: 0; 1 Complications: 25%; 75% (*P*=0.05) Mortality: 0; 1	Financial disclosure was not reported Retrospective; small sample size; patients chose surgical method; BMI and surgical history not reported
Kang 2011b	Retrospective cohort	15 Robotic, 5 Open, 10	*Robotic; Open* Mean age: 50±12.3 yrs; 38.7±16.5 yrs (NS) Men/Women: 5/0; 4/6 Symptomatic: 0; 7 (*P*=0.026) Inclusion: Central pancreatectomy; Borderline malignant tumor	Robotic Open Median follow-up 19 mos	*Outcome: Robotic; Open* Operating time: 432.0±65.7 mins; 286.5±90.2 mins (*P*=0.013) Blood loss: 275.0±221.7 mL; 858.3±490 mL (P=0.038) Transfusion: 0; 3 (NS) Reoperation: 0; 2 (NS) HLOS: 14.6±7.7 days; 22.1±13.3 days (NS) Complications: 1; 5 (NS)	Poor Retrospective; small sample size; possible age-related selection bias favoring control group; BMI and surgical history not reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
			in the neck or proximal body of the pancreas Exclusion: None reported		No mortalities Diabetes during follow-up: 0, 0	
Waters 2010	Retrospective cohort (chart review of prospectively collected data)	57 Robotic, 17 Laparoscopic, 18 Open, 22 Operative approach according to surgeon and patient preference.	*Robotic; Laparoscopic; Open* Mean age (yrs): 64; 59; 59 (NS) Men (%): 35%; 50%; 45% (NS) ASA score, specimen length: Similar Lesion sizes: Smaller in robotic group; global *P*=0.01 (radiographic measurement) and global *P*=0.06 (pathologic measurement) Indications: Overall	Robotic Laparoscopic, Open Hospital discharge	*Intraoperative outcomes: Robotic; Laparoscopic; Open* Positive margins (n): 0, 0, 2 Lymph nodes obtained (n): 5, 11, 14 (global *P*=0.04) Spleen preservation (%): 65%, 28%, 14% (*P*=0.04 for robotic vs. laparoscopic) Splenic artery and vein preserved (%): 65%, 18%, 9% (*P*=0.006 for robotic vs. laparoscopic) Conversion rate (%): 12%, 11%, N/A (NS) Blood loss (mL): 279, 667, 681 (overall difference, NS)	Fair quality cost analysis but Poor quality operative outcome data No disclosure of conflicts of interest or funding source Retrospective; small sample size; potential bias from unsystematic assignment to operative approach; results may

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			differences in indication were NS, but 50% open and none of robotic procedures were for adenocarcinoma. *Inclusion criteria:* Pancreatectomy during 1-yr time frame *Exclusion criteria:* Emergent or urgent surgery, concurrent major surgery, surgery indicated for pancreatitis		Operative time (min and 95% CI): 298 (191-418), 224 (100-346), 234 (136-437) (global *P*=0.01) *Postoperative outcomes: Robotic; Laparoscopic; Open* HLOS (day and 95% CI): 4 (2-6); 6 (3-34); 8_3-25) (global *P*=0.04) Morbidity (%): 18%, 33%, 18% (overall, NS) U.S. hospital perspective; direct variable costs, excluding professional costs. Costs from hospital accounting records, collected August 2008 – August 2009; operative time and supplies, anesthesia, nursing, laboratory, overall hospital stay. Adjusted operative costs include	not generalize to patients requiring surgery for pancreatitis or to surgeons without prior training and experience

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
					amortized cost of robotic system. Post discharge and other follow-up care excluded. Intent-to-treat analysis. *Costs: Robotic; Laparoscopic; Open* Operative, unadjusted: $4898; $3072; $3510 (global *P*=0.04) Operative, adjusted: $6214; N/A; N/A Hospital stay: $5690; $9828; $12;011 (global *P*=0.01) Total, unadjusted: $10,588; $12,900; $15,521 (NS) Total, adjusted: N/A; N/A; $11,904 (NS for comparison of adjusted robotic with other unadjusted costs)	

Prostatectomy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
CADTH 2011	SR + MA N = 21,470 *Da Vinci* (N=11,196) Open radical prostatectomy (N=3,212) Open radical retropubic prostatectomy (N=1,920) Open radical perineal prostatectomy (N=91) Laparoscopic radical prostatectomy (N=1,149) Radical retropubic prostatectomy (N=2,736) Radical perineal prostatectomy (N=16) Retropubic total prostatectomy (N=29) Transperitoneal laparoscopic prostatectomy (N=213) Conventional prostatectomy (N=152) 24 Prospective observational studies 27 Retrospective comparison studies	Robotic prostatectomy Open or laparoscopic surgery Follow-up 6 weeks to 58 months	MA findings for RARP compared with ORP *Longer operative duration* (WMD 37.74 minutes, 95% CI 17.13 to 58.34); *Shorter length of hospital stay* (WMD −1.54 days, 95% CI −2.13 to −0.94); *Reduction in positive margin rate in pT2 patients* (RR 0.6, 95% CI 0.44 to 0.83, NS). The results of this comparison in pT3 patients and in two trials that did not report pT2 and pT3 subclasses, was inconclusive;	Good quality SR SR included 1 high quality, 6 good quality, 35 fair to good quality, 6 poor to fair quality, and 1 poor quality studies.

			Reduction in the extent of blood loss (WMD −470.26 mL, 95% CI −587.98 to −352.53) *Reduced risk of red blood cell transfusion* (RR 0.20, 95% CI 0.14 to 0.30); *Urinary continence after 12 months* (RR 1.06, 95% CI 1.02 to 1.10, NS); and *Likelihood of sexual function after 12 months* (RR 1.55, 95% CI 1.20 to 1.99). MA Results for RARP compared with LPR: *Shorter operative duration* (WMD −22.79 minutes, 95% CI −44.36 to −1.22); *Shorter length of hospital stay* (WMD −0.80 days, 95% CI	

				−1.33 to −0.27); *Positive margin rate comparisons* were inconclusive for pT2 and pT3; *Reduction in the extent of blood loss* (WMD −89.52 mL, 95% CI −157.54 to −21.49); *Reduced risk of red blood cell transfusion* (RR 0.54, 95% CI 0.31 to 0.94, NS); *Urinary continence after 12 months*, pooled estimates trended in favor of RARP (RR 1.08, 95% CI 0.99 to 1.18, NS).	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Kasraeian 2011	Retrospective cohort design	N=4000 Robotic n= 200	Robotic, laparoscopic, p-	RALP vs. LRP	Comparison of RALP vs. LRP, p-value	Good quality

		Laparoscopic n = 200	value Median (range) age 60.8 (44-73), 61.9 (45-75), 0.067 Median (range) BMI 24.9 (19.1-34), 25.7 (19.1-56.3), 0.003 Prostate size 50 (27-122), 55 (21-136), <0.001 PSA 6.4 (2.1-19.8), 6.8 (2.7-48.8), <0.001 Median stage T1c, T1c, 0.578 Median Gleason score 6, 6, 0.317	Follow-up n/a	*Median (range) operating time, min* 120 (60-240), 150 (75-300), <0.001 *Median (range) est. blood loss, mL* 350 (50-1500), 400 (50-1300), 0.069 *Median (range) hospital stay, days* 4 (3-11), 4 (3-23), 0.056 *Nerve-sparing, n%* 197 (98.5), 177 (88.5), <0.001 *Non-nerve-sparing, n(%), mL* 3 (1.5), 23 (11.5), <0.001PSM rate similar between groups 13.5% vs. 12% (NS) however in different locations…LRP were mostly at apex	

					(53.8%; p=0.038) while posterolateral after RALP (48%; p=0.046); Median margin size: 2mm vs. 3.5mm; (p=0.041)	
Kim 2011a	Comparative Prospective	763 Robotic n = 528 Open n = 235	Robotic, open, p-value Age 64.2 ± 7.3, 66.5 ± 5.7, p<0.001 Mean PSA 10.4 ± 16.0, 14.6 ± 22.1, p=0.003 Mean BMI 24.5 ± 2.7, 25.1 ± 3.6, p=0.014 Mean membranous urethral length 1.15 ± 0.32, 1.11 ± 0.30, p = 0.042 Pts receiving neoadjuvant	RARP vs. Open (RRP) Pts serially followed post-operatively for comparative analysis	Continence and potency recovery were checked serially by interview and questionnaire at 1, 3, 6, 9, 12, 18, and 24 mo postoperatively After the initial 132 cases, pts who underwent RARP demonstrated faster recovery of urinary continence compared to RRP pts. Potency recovery was more rapid in the RARP group at all evaluation time points, beginning from the initial cases. In multivariate analysis, younger age & longer preoperative	Poor quality favoring robot Limitations: Non-randomized; used interview to evaluate potency recovery 2 groups were dissimilar in age, neoadjuvant hormone therapy use, nerve-sparing surgery frequency , pre-op PSA levels

			therapy (%) 49 (9.3), 41 (17.4), p= 0.007 Clinical stage less advanced in robotic group, p = 0.004 Gleason score lower in robotic group, p=0.004 NS differences in mean testosterone, tumor volume		membranous urethral length seen by prostate MRI demonstrated statistical significance as independent prognostic factors for continence recovery; younger age, surgical method (RARP vs. RRP), and higher preoperative serum testosterone were independent prognostic factors for potency recovery. **Conclusions:** Patients after RARP demonstrated superior functional recovery. Moreover, membranous urethral length on preoperative MRI and patient age were factors independently predictive of continence recovery, while patient age and	

					higher preoperative serum testosterone were independent prognostic factors for potency recovery.	
Tollefson 2011	Retrospective cohort study	5908 Robotic n = 1084 Retropubic radical prostatectomy n = 4824	Robotic, open, p-value Median age (range) 60 (38-81), 61 (31-84), 0.012 Median (range) BMI 27.8 (18.9-60.3), 27.5 (16.2-56.8), 0.094 Biopsy Gleason score 12, 57, <0.001 Median Pre-op PSA (range), ng/mL 5.0 (0.1-42.3), 5.4 (0.1-194), <0.001	RARP vs. RRP Follow-up: at least 30 days	Comparison of RARP vs. RRP, p-value *Incidence of surgical site infection* 6 (0.6%), 216 (4.6 %), <0.001 *Incidence of urinary tract infection* 17 (1.6%), 58 (1.2%), NS *Sepsis/bacteremia* 1 (0.1%), 7 (0.1%), NS	Poor quality Baseline characteristics favored robotic group
Masterson 2011	Retrospective cohort	N=1041 Robotic n=669 Open n=357	Robotic; open; p-value Mean preoperative	Open Robotic	Robotic; open; p-value NS differences between groups in	Fair quality Non-randomized

			PSA, ng/mL 7.1; 7.6; p=0.02 Mean prostate weight, g 48.2; 44.2; p<0.01 % lymph node involvement 8; 1; p=0.001 NS differences between groups in age, tumor volume, largest tumor dimension, Gleason sum, pathologic stage, +SM, benign capsular incision Exclusion criteria Pts receiving neoadjuvant or adjuvant therapy w/androgen deprivation, radiation or chemotherapy (n=6); pts		+SM location for all patients Mean +SM length in mm (range) for all patients 3.0 (0.05, 17.5); 5.6 (0.1, 38); p=0.04 NS differences in +SM location for pT2, pT3, bilateral NVB preservation patients Biochemical recurrence-free survival 24-months 87%; 87%; NS 60-months 73%; 71%; NS	retrospective design, though consecutive pts were enrolled; experience of surgeon may have biased towards open group; no comorbidities or other health indicators included in analysis which may have introduced bias (direction unknown) Single pathologist and single surgeon for all cases

			undergoing radical perineal (n=2), open salvage (n=2), and pure laparoscopic RP w/o robotic assistance (n=5)			

Pyeloplasty

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Thavaneswaran 2009	SR Four non-randomized comparative studies N=224 Robotic n = 77 Laparoscopic n = 147 Link 2006 (n=20) Yanke 2008 (n=145) Weise 2006 (n=45) Bernie 2005 (n=14)	Robotic pyeloplasty Laparoscopic pyeloplasty Follow-up ranged 5.6 months to 24 months	Operative time (min) Study; Robotic [SD] or (range), Laparoscopic [SD] or (range) Link; 100.2 (9.1), 80.7 [21.9], p=0.018 Yanke; NR Weise; 271 (207-444), 299 (193-376), NS Bernie; 324 (252-420), 312 (240-390), NS EBL (mL) Study; Robotic (range), Laparoscopic (range) Link: P=NS (data not provided) Yanke: NR Weise; <100 (10-300), <100 (20-200), NS Bernie; 60(50-100), 40(5-200), NS	Good quality SR SR notes that all four studies describe objective clearly. None were randomized or blinded. One study rated as III-2 level of evidence; Three studies rated as III-3 level of evidence

			LOS (days) Study; Robotic (range), Laparoscopic (range) Link: P=NS (data not provided) Yanke NR Weise; 2 (1-3), 2 (2-5), NS Bernie; 2.5 (2-6), 3 (2-4), NS Conversions, n/N (%) Link NR Yanke NR Weise; 0/31 (0%), 0/14 (0%), NS Bernie NR Surgical success rate, n/N (%) Link; 10/10 (100%), 10/10 (100%), NS Yanke; 29/29 (100%), 103/116 (88.8%), p=NR Weise; 19/29 (66%), 7/11 (64%), p=NR Bernie; NR	

			Complications, n/N (%) Link; 1/10 (10%), 0/10 (0%), p=NR Yanke; NR Weise; 2/31 (6%), 2/14(14%), p=NR Bernie; 2/7 (28.6%), 2/7 (28.6%), NS Pain: Study: robotic; laparoscopic Weise: 83% no pain, 14% mild, 3% significant; 73% no pain, 27% mild pain, 0% significant pain Renal function: Bernie: improvement 30-44% both groups Weise: robotic 44% had significant improvement, 52% no change, 4% decrease; laparoscopic 25% improved, 75% no change, 0%	

					decreased.	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Bird 2011	Retrospective cohort	172 Robotic, 98 Laparoscopic, 74	*Robotic; Laparoscopic* Mean age: 39.6±15.2 yrs; 39.8±13.9 yrs (NS) Men/Women: 46/52; 35/39 BMI: 25.7 kg/m^2; 26.0 kg/m^2 (NS) Secondary uteropelvic junction obstruction: 17.3%; 6.8% (*P*=0.04) Inclusion: Uteropelvic junction obstruction; transperitoneal approach Exclusion:	Robotic Laparoscopic Long-term follow-up (not defined)	*Outcome: Robotic; Laparoscopic* Operating time: 189±62 mins; 187±69 mins (NS) Blood loss: <50 mL; < 50 mL HLOS: 2.5 days; 2.5 days (NS) Intraoperative and postoperative complications: similar Radiographic success rate at follow-up: 93.4%; 95% 136/172 pts (79%) at long-term follow-up	Poor Financial disclosure was not reported Retrospective; baseline clinical difference between groups; high dropout rate for long-term f/u

Link 2006	Prospective nonrandomized trial (10 consecutive pyeloplasties performed with robotic system; next 10 performed laparoscopically)	20 Robotic, 10 Laparoscopy, 10	*Robotic; Laparoscopic* Mean age: 47 yrs, 38 yrs (NS) BMI: 23, 24 (NS) Men (%): 30%, 40% Surgical side, presence of crossing vessels, and need for renal pelvic reduction were similar *Inclusion criteria:* Primary uretropelvic junction obstruction and scheduled for laparoscopic dismembered pyeloplasty *Exclusion criteria:* Previous ipsilateral renal surgery	Robotic Laparoscopic Mean 5.6 mos (too short to allow comparison of failures) Single surgeon performed all procedures; had previously performed >20 robotic procedures, including 3 for pyeloplasty.	*Operative outcomes contributing to cost differences:* Greater total room time for robotic procedures (173.8±15.4 min vs. 134.8±20.6 min, *P*<0.001) (total operative time [100.2±9.1 min vs. 80.7±21.9 min; P=0.018] and all other components were greater for robotic procedures; also, no robot docking or undocking time for laparoscopic procedures). No differences in complications or blood loss. No learning curve was detected. U.S. hospital (academic) perspective. All direct/indirect inpatient costs: (a)	Fair quality cost analysis but poor quality outcomes data No disclosure of conflicts of interest or funding source. Nonrandomized treatment assignment (although temporal bias unlikely given the short time frame);possible bias in favor of laparoscopic group if robotic procedures were the first for pyeloplasty; results would not generalize to smaller institutions unable to maintain the

					operating room (direct and indirect costs for second half 2004 from hospital accounting system); (b) anesthesia professional fees (2004 Medicare rates); (c) disposables (costs, not charges); (d) amortized cost of robotic system (5 years; assume 150 cases/year); and (e) amortized cost of laparoscopy video tower equipment (5 years; 400 cases/year). Factors that did not differ between robotic and laparoscopic in a previous cost comparison were excluded (e.g., surgeon professional fees, per diem hospital stay costs, analgesics, postoperative visits,	assumed volume of procedures

					and standard laparoscopic instruments used in both types of procedure). Operative data collected March-November, 2004. *Cost: Robotic; Laparoscopic* Total: $5324, $1990 (graphic display of SD values indicated no overlap in CIs) Mainly due to differences in total room time (134 min vs. 135 min, P<0.0001) and consumables: ($934 vs. $73; testing not reported) *One-way sensitivity analysis:* (a) Laparoscopic operative time (one component of total time) would have to	

					increase from 81 to 388 min for costs to be equivalent. (b) With elimination of robotic system depreciation costs, robotic surgery was still 1.7 greater than laparoscopic. (c) Increasing use of robotic system to 400 cases/year would decrease per-case depreciation costs from $2000 to $750.	

Rectopexy

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Maeso 2010	SR 1 non-randomized controlled study N=33 Robotic n = 14 Laparoscopic n = 19 Heemskerk (n=33)	Robotic rectopexy Laparoscopic rectopexy	No meta-analysis performed (only 1 study identified) Length of surgery (min) Robotic = 39 minutes longer LOS = 4 days both groups Conversions: Robotic = 5% Laparoscopic = 0% Time to defecation, postoperative constipation or incontinence = NSD Cost = €600 more for robotic procedures	Good quality SR SR notes that study was not randomized or blinded, and that objective was clearly stated. Significant difference in age between treatment groups; effect on results not described. SR concludes that based on one study, robotic procedure is slower and more costly

Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Wong 2011	Retrospective cohort	63 Robotic, 23 Laparoscopic, 40	*Robotic; Laparoscopic* Mean age: 61±11 yrs; 59±13 yrs (NS) BMI: 27 kg/m2; 24 kg/m2 (*P*=0.03) Inclusion: Symptomatic complex rectocele; conservative treatments ineffective Exclusion: Complete rectal prolapsed; isolated internal rectal prolapse	Robotic Laparoscopic Follow-up: 6 mos	*Outcome: Robotic; Laparoscopic* Operating time: 221±39 mins/ 162±60 mins (*P*=0.0001) Blood loss: 6±23 mL; 45±91 mL (*P*=0.048) Conversion to open procedure: 1; 4 (NS) Postoperative complications: 0; 5 No mortalities or recurrences	Poor Retrospective; small sample size; patients assigned to robotic group based upon availability of robot; Robotics group had higher BMI
de Hoog 2009	Retrospective cohort	82 Robotic, 20 Laparoscopic, 15 Open, 47	Mean age: 56.4 yrs, range 21-88 Men/Women: 11/71	Robotic Laparoscopic Open Procedure Mean follow-up 1.95 yrs	*Outcome: Robotic; Laparoscopic; Open* Operating time: 154±47 mins; 119±31 mins; 77±33 mins (all analyses	Poor Retrospective; small sample size; varied

			Inclusion: Full-thickness rectal prolapse Exclusion: <18 yrs of age; patients with history of extensive abdominal surgery were ineligible for robotic or laparoscopic procedures		*P*≤0.02) HLOS: 2.6 days, range 1-6; 3.5 days, range 1-14; 5.7 days, range 2-30 (*P*<0.001) Recurrence: 20%; 27%; 2% (*P*=0.008) OR for recurrence: laparoscopic vs. open, 13.94 (95% CI 0.9, 215.6); robotic vs. open, 24.41 (95% CI 1.45, 410.7)	entry criteria for different surgical methods; operative data not presented per procedure type

Roux-en-Y Gastric Bypass

Review				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Maeso 2010	SR/MA 1 RCT 3 non-randomized comparative studies N=321 Robotic n = 121 Laparoscopic n = 200 Sanchez (n=50) Hubens (n=90) Artuso (n=161) Mohr (n=20)	Roux-en-Y robotic Roux-en-Y laparoscopic	**Meta-analysis results:** Total conversions: OR = 9.46 (1.72, 52.15) favoring laparoscopy Surgery time (min) MD = 10.12 (-69.86, 90.11) NS Complications OR = 0.58 (0.21, 1.64) NS Open conversions RD = 0.06 (-0.04, 0.16) Outcomes reported in SR but not included in MA: Cost: Robotic €1,000 more expensive	Good quality SR Sanchez RCT rated as good quality by SR; other three studies not randomized or blinded. Artuso and Hubens did not compare baseline characteristics. SR concludes robotic and laparoscopic procedures have similar surgery times, length of stay, number of complications, but robotic procedure has more surgical conversions

					Learning curve: Mohr: Robotic learning curve less steep than laparoscopic Sanchez: Surgery time in continuous groups of 10 patients, Robotic/Laparoscopic (min): 154, 124, 99 / 163, 141, 139 Artuso: learning curve present (data not reported) Hubens: last 10 robotic patients similar to laparoscopic (136m vs. 127m)	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Ayloo 2011	Chronologically determined controls (45 laparoscopic procedures followed by 90	135 Robotic, 90 Laparoscopic, 45	*Robotic; Laparoscopic* Mean age: 39±9 yrs; 43±8 yrs (*P*=0.01) Men/Women:	Robotic Laparoscopic Follow-up: 1 yr	*Outcome: Robotic; Laparoscopic* Operating time: 207±31 mins; 227±31 mins (*P*=0.0006) HLOS: 2; 3	Poor Financial disclosure was not reported Retrospective review;

	robotic over 3-year time frame)		12/78; 3/42 (NS) BMI: 48 kg/m^2; 46 kg/m^2 (NS) Weight: 137±23 kg; 132±21 kg (NS) Inclusion: Morbid obesity; surgical indication criteria of NIH Exclusion: Not reported		(*P*=0.0002) Reoperation: 1; 1 (NS) Readmission: 5; 1 (NS) Early morbidity: 1.1%; 1.2% (NS) Late morbidity: 1.1%; 8.8% (*P*=0.04) There were no conversions to open surgery, transfusions, or fatalities. Difference between groups in weight loss at 3 mos, 6 mos, and 1 yr was not statistically significant	noncontemporaneous controls; patients in robotic group were slightly younger and slightly more obese than laparoscopic group; choice of surgical method was made chronologically; weight loss data not reported for laparoscopic group; no data on comorbidities
Park 2011	Retrospective cohort	300 Robotic: 105 Laparoscopic: 195	*Robotic; Laparoscopic* Mean age: 42.2±11 yrs; 43.9±10.9 yrs (NS) Men/Women: 22/83; 54/141 (NS) BMI: 46.8	Robotic Laparoscopic Follow-up: 1 yr	*Outcome: Robotic; Laparoscopic* Operating time: 169±38 mins; 152±50 mins (*P*=0.003) Blood loss: 59.0±43.8 mL; 57.2±45.9 mL (NS) HLOS: 3.4 days; 3.0 days (NS)	Poor One author receives honoraria from a manufacturer of surgical instruments Retrospective; procedure for assigning patients to

			kg/m^2; 47.7 kg/m^2 (NS) Comorbidities and ASA were similar Inclusion: Morbid obesity Exclusion: Not reported		Conversion to open procedure: 0; 3 (1 robotic procedure was converted to a laparoscopic procedure) Complications: 9.5%; 9.7% (NS) Follow-up: 61.9%; 66.2% Weight loss at 1 yr: 61.9%; 61.3% (NS) Total hospital charges: similar (no detail provided)	surgical method was not reported; high dropout rate for 1-year results
Sanchez 2005 (analyzed by BMI)	Randomized, controlled trial	50 Robotic: 25 Laparoscopic: 25	Robotic; Laparoscopic Median age: 43.3 yrs, range 27-58; 44.4 yrs, range 20-59 (NS) Men/Women: 2/23; 3/22 BMI: 45.5 kg/m^2; 43.4 kg/m^2 (NS) Comorbidities and history of prior	Robotic Laparoscopic No follow-up	*Outcome: Robotic; Laparoscopic* Operating time: 130.8 min; 149.4 min (*P*=0.02) Operating time/BMI: 2.94; 3.47 (*P*=0.02) Operating time in patients with BMI >43 kg/m^2: 123.5 mins; 153.2 mins (*P*=0.009) Operating time/BMI in patients with BMI >43 kg/m^2: 2.49; 3.24	Good Financial disclosure was not reported Small sample size; randomization and concealment method were not reported;

			abdominal surgery were similar Inclusion: Surgical indication criteria of NIH Exclusion: Not reported		(*P*=0.009) HLOS: 2.72; 2.72 (NS) 1 robotic procedure was converted to a laparoscopic procedure No postoperative complications	
Hagen 2011	Retrospective cohort with cost analysis	N=990 Open n=524 Laparoscopic n=323 Robotic n=143	NS differences in age, gender, BMI between all three groups Significant differences between open and robotic groups in ASA scores (robotic group having lower scores); NS difference between laparoscopic and robotic groups Cost inputs:	Laparotomy Laparoscopic Robotic	NS differences between all groups in overall complications, pulmonary complications, death, bleeding, wound infections, neurologic complications, other complications NS differences between open and robotic groups in anastomotic leaks, anastomotic strictures, or reoperations Laparoscopic vs.	Poor quality cohort Poor quality cost analysis Authors declare employment and consult work with Intuitive; differences in ASA scores at baseline (robotic patients were healthier), possibly introducing bias in favor of robotic group; retrospective study design. Temporal distribution between groups not discussed, but study

			OR material costs Laparotomy, laparoscopy, robotic Drapes 112.84; 147.36; 546.22 Staplers 1860.95; 3560.83; 1860.95 Other instruments 187.1; 1737.84; 1368.01 Robot-specific costs = 1582.91 Suturing material 90.45; 48.076; 69.37 Total costs 2251.34;		robotic, p-value Anastomotic leaks, n (%) 13 (4.0) vs. 0 (0), p=0.0349 Anastomotic strictures, n (%) 22 (6.8) vs. 0 (0), p=0.0002 Conversions, n (%) 16 (4.9) vs. 2 (1.4), p=0.0388 Reoperations, n (%) 13 (4.0) vs. 1 (0.7), p=0.0349 Hospitalization outcomes Laparotomy; laparoscopy; robotic ICU stay, mean 2.0; 0.6; 0.2, p<0.0001 (open vs. robotic), p=0.0517 (laparoscopic vs. robotic)	period included cases post-1997, possibly introducing bias towards robotic group, which was likely operated on more recently. No discussion of surgeon experience between groups, which may introduce bias of unknown direction. Cost analysis limitations include use of only direct costs, only selected variables included in sensitivity analysis, unknown source of cost inputs, potential differences in health system costs (data from Switzerland) when compared to US practice

			5494.11; 5427.46		Length of hospital stay: 10.9; 11.0; 7.4, p<0.0001 (open vs. robotic), p=-0.001 (laparoscopic vs. robotic) Cost analysis findings Laparotomy; laparoscopy; robotic Baseline costs $23,000; $21,697; $19,363 Robotic procedure cheaper when at least 7 procedures performed, assuming anastomotic leak rate of 4%; 10 robotic procedures must be performed if laparoscopic leak rate reduces to 2% With 4% leak rate, OR time could be up to 135 minutes longer without	

					exceeding costs of laparoscopy; 30 minutes longer with 2% leak rate	

Sacrocolpopexy

Reviews				
Reference	**Study Design and Number of Studies and Subjects**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Reza 2010	SR/MA 1 prospective study using historical controls N = 178 Robotic n = 73 Open n = 105 Geller 2008 (n = 178)	Robotic sacrocolpopexy Open sacrocolpopexy	Meta-analysis not performed (only 1 study identified) Outcomes reported in SR: EBL (mL) [SD] Robotic = 109 [93] Open = 255 [155] P<0.001 HLOS (days) Robotic = 1.3 [0.8] Open = 2.7 [1.4] P<0.001 Duration of surgery (min) Robotic = 328 [55] Open = 225 [61] P<0.001 Postoperative fever Robotic = 4%	Good quality SR SR notes that study was not randomized or blinded, but had a clear objective. No other quality indicators discussed.

					Open = 0% P<0.04	
Individual studies (published after review)						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Paraiso 2011	Randomized, controlled trial	78 Robotic, 40 Laparoscopic, 38	*Robotic; Laparoscopic* Mean age: 61±9 yrs; 60±11 yrs BMI: 29 kg/m^2; 29 kg/m^2 History of pelvic surgery was similar Inclusion: Posthysterectomy vaginal apex prolapsed; ≥21 yrs of age; preferred laparoscopic method Exclusion: History of sacrocolpopexy; pelvic inflammatory disease; morbid obesity; rectal	Robotic Laparoscopic Follow-up: 1 yr	*Outcome: Robotic; Laparoscopic* Operating time: 265±50 mins; 199±46 mins (95% CI 43, 90) Conversion to another procedure: 3; 2 (NS) HLOS: 43 hrs; 34 hrs (95% CI -4, 23) Total healthcare system cost : $16,278±3326; $14,342±2941 (*P*=0.008; 95% CI 417, 2941); driven by difference in operating room cost ($1667; 95% CI 448, 2885; P=0.008) Costs of hospitalization and 6-wk postoperative care were similar. Cost data in 2011 U.S.	Fair Small sample size; high 1-year dropout rate

			prolapsed		dollars collected health from system-wide (multispecialty clinic) accounting system; all direct and indirect costs, except initial purchase and maintenance of robotic system, for procedure related care through 6-week postoperative visit were included. Intraoperative and postoperative complications were similar Narcotic use, return to daily activities, anatomic outcome, and quality-of-life measures were similar Patients in robotic group reported significantly more pain and used more NSAIDS at 3-5 wks postoperatively than the laparoscopic group (all analyses $P \leq 0.04$)	

White 2009	Retrospective cohort with matched controls (cases were single port procedures from a prospectively collected database; robotic and laparoscopic were retrospectively matched)	30 Robotic, 10 Laparoscopic, 10 Single port, 10	*Robotic; Laparoscopic; Single port* Mean age: 61.3 yrs; 62.5 yrs; 59.5 yrs (NS) BMI: 26.0 kg/m^2; 27.6 kg/m^2; 25.8 kg/m^2 (NS) Prior prolapse surgery and prolapse stage were similar Inclusion: Symptomatic ≥stage II pelvic organ prolapse Exclusion: Not reported Patients in robotic and laparoscopic group chosen by age and BMI matching to single port group	Robotic Laparoscopic Single port laparoscopy Follow-up: 6 mos	*Outcome: Robotic; Laparoscopic; Single port* Operating time: 150±16 mins; 151±19 mins; 162±25 mins (NS) Blood loss: 87 mL; 65 mL; 47.5 mL (P=0.5) HLOS: 1.6 days; 1.6 days; 1.5 days (NS) Reoperation: 0; 0; 3 No complications 90% of patients completed follow-up (treatment group was not specified) At follow-up, all patients reported symptom relief and had excellent prolapsed reduction based upon pelvic organ prolapsed questionnaire.	Poor (especially for 6-mo outcomes) Financial disclosure was not reported Retrospective; noncontemporaneous controls (but short time frame); small sample size; follow-up data not shown; standard deviation was not always reported
Patel 2009	Retrospective cohort	15 Robotic, 5	*Robotic; Laparoscopic;*	Robotic Laparoscopic	*Operative outcomes: Robotic; Laparoscopic;*	Fair quality cost analysis

		Laparoscopic, 5 Open, 5	*Open* Median age: 58, 58, 56 Median BMI: 28, 24, 28 # vaginal deliveries: 3, 2, 3 Prolapse stage and # prior prolapsed surgeries: Same across groups Inclusion criteria: None other than sacrocolpopexy Exclusion criteria: Concurrent hysterectomy, other, incontinence procedures, or other types of pelvic reconstruction (concurrent paravaginal defect repair or Burch, posterior colporrhaphy, or	Open	*Open* Blood loss (cc): 210±74.2, 150±61.2, 235±134.2 (NS) Operative time (min): 358±86, 510±372, 418±249 (NS) # nights in hospital: 2±0, 3±1.3, 3±2.7 (NS) Cost-minimization analysis, assuming equivalent follow-up outcomes, was conducted. Costs included all direct and indirect costs associated with procedure and inpatient stay. Data from procedures performed 2002 through 2007 were inflation-adjusted using Consumer Price Index. *Costs: Robotic; Laparoscopic; Open* Operating room,	Poor quality outcomes data Retrospective and nonsystematic treatment assignment; very small sample size; patients undergoing laparoscopy were less obese; 56 of 71 sacrocolpopexies were excluded because of concurrent procedures, so results may not be generalizable to typical practice; costs adjusted by general rather than medical index

			cystourethroscopy was eligible)		direct: $4520.63±1874.59; $3141.79±2130.00; 1594.22±353.14 (global *P*=0.48)* Instruments/materials, direct: $2207.88±292.69; $1940.55±514.79; $465.01±553.36 (global *P*=0.0001)* Anesthesia, direct: $426.93±121.09; $503.82±73.56; $36.00±126.49) (NS) Miscellaneous, direct: $136.51±28.43; $186.15±181.32; $152.27±108.12 (NS) Hospital room, direct: $853.39±18.26; $1043.21±420.98; $959.30±405.19 (NS) Indirect: Comparable between robotic and laparoscopic; slightly greater than open but difference NS. Total direct and	

					indirect: $12,525.50±2519.38; $11,093.90±6123.73; $6816.90±1696.79 (global *P*=0.098) *Robotic and laparoscopic significantly greater than open Charges: $24,162; 19,309; $13,150 (global *P*=0.004) Reported profits followed the same pattern as total costs and charges, but the method of calculation was not clear.	
Judd 2010	Cost-minimization analysis; decision analytic model (equivalent clinical effectiveness assumed, based on a previously published	N/A	Hypothetical cohort of women with advanced pelvic organ prolapse electing sacrocolpopexy with synthetic polypropylene mesh. Model included 4 outcomes: (a) operative time;	Robotic Laparoscopic Abdominal (open) No follow-up after discharge	U.S. healthcare system perspective, 2008 dollars. Professional fee costs derived from Medicare rates for professional anesthesia and surgeon services. All other inpatient costs incurred at Duke medical center: peri- and postoperative	Poor Outcome and cost data from different sources; no data on assumed surgical risk of patients (possibly unreliable operative outcome estimates); unclear whether fixed costs were included; absolute results

	retrospective cohort study [Geller 2008] showing equivalent vaginal vault support at 6 weeks between robotic and abdominal approach and the similarity of the procedure performed through the 3 different routes)		(b) possibility for both robotic and laparoscopic procedures of conversion to an abdominal (open) procedure; (c) blood transfusion (but not enterotomy or ureteral injury); (d) HLOS. Parameters (base case values and ranges for sensitivity analyses) for these outcomes were derived from 7 observational studies identified in a systematic literature review (PubMed; February 2009) and from expert opinion where necessary; key sources were		services; disposables; transfusion packs; extra time and fewer laparoscopic instruments for conversion (calculated differently for early* and late conversions); laboratory; pharmacy (varied according to surgical approach; Medicare Part B maximum allowable and online prices); room and board (billing department); robotic system purchase ($1.65M) plus maintenance years 2-5 ($149,000/year), amortized over 7 years with 5% interest rate and distributed to each procedure, assuming 24 robotic procedures/month (robotic system costs excluded from the Existing Robot Model).	would not generalize to smaller institutions with lower volumes of robotic procedures

			Geller 2008 and Paraiso 2005.		Cost-charge ratio of 0.6 applied where necessary. *Total cost: Robotic; Laparoscopic; Abdominal* Existing Robot Model (hospital already owns): $8508, $7353, $5792. Only extreme reduction in robotic operative time or extreme reduction in robotic disposables combined with extreme increase in laparoscopic disposables predicted equivalent cost between robotic and laparoscopic Robot Purchase Model: $9962, $7353, $5792 Sensitivity analyses showed no situations in which robotic became less expensive than laparoscopic.	

Tan-Kim 2011	Retrospective cohort	104 Robotic, 43 Laparoscopic, 61	*Robotic; Laparoscopic* Mean age: 60 ± 8 yrs; 65 ± 8 yrs (p<0.01) History of pelvic surgery (not including hysterectomy) was similar Inclusion: women with post-hysterectomy sacroplexy using one of minim Exclusion: History of concurrent hysterectomy and/or anterior vaginal wall repair	Robotic Laparoscopic Follow-up data recorded at 3 wks and all follow-up visits (variable length 6-12 mos.)	*Outcome: Robotic; Laparoscopic* Operation time: 281 ± 58 mins; 206 ± 42 mins (p< 0.001) Costs: Robotic surgery costs significantly higher than laparoscopic (p<0.01;for 2724 vs. 2295 standard "cost units"). Costs for hospital stay were similar. Median hospital stay, mean follow-up and patients with mesh erosion were similar Complications (intraoperative and postoperative) were similar.	Poor small sample size; limited long term follow-up outcomes; CIs not provided; no financial disclosure
Seror 2011	Prospective cohort	67 Robotic, 20 Laparoscopic,	*Robotic; Laparoscopic*	Robotic Laparoscopic	*Outcome: Robotic; Laparoscopic*	Poor Different baseline

		27	Mean age: 60 yrs; 66.7 (p=0.05) BMI and history of gynecological surgery were similar	Follow-up at 1, 3, 6 mos and annually. Also as needed for urinary symptoms	Blood loss: 55 vs. 280 ml (median) (p= 0.03) Operation time (125 vs. 220 min. p = 0.03) but overall operation room time similar No significant difference between hospital stay, amount of pain medicines, hospital stay or median length of follow-up	population characteristics Small sample size Different baseline populations Short term outcomes

Splenectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Bodner 2005	Retrospective cohort	12 Robotic, 6 Laparoscopic, 6	*Robotic; Laparoscopic* Median age: 42 yrs; 62 yrs (NS) Women/Men: 2/4; 0/6 BMI: 27 kg/m^2; 26.3 kg/m^2 ASA score, platelet counts, and previous abdominal surgery were similar Inclusion: First 6 robotic or first 6 laparoscopic splenectomies by surgeon Exclusion: Not reported	Robotic Laparoscopic Mean follow-up: Robotic, 11 mos; Laparoscopic, 21 mos	*Outcome: Robotic; Laparoscopic* Operating time: 154 mins, range 115-292; 127 mins, 95-174 (*P*<0.05) HLOS: 7; 6 (NS) Blood loss was similar There were no conversions to open surgery or major complications 1 pt in laparoscopic group died 14 mos postoperatively (unrelated to splenectomy) All other patients were asymptomatic relative to surgery Overall procedural cost: $6927; $4084 (*P*<0.05) Cost difference attributed to longer operation time, use of	Poor Financial disclosure not reported Retrospective; very small sample size

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
					special instruments, and disposable supplies (total $2843) in robotic group. Initial cost of robotic system was not added into cost determinations but maintenance costs were included.	

Thymectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Ruckert 2011	Retrospective cohort w/ historic controls (79 thoracoscopic procedures followed by 74 robotic over 12-year time frame)	153 Robotic, 74 Thoracoscopic, 79	*Robotic; Thoracoscopic* Median age: 39 yrs, range 7-75; 37 yrs, range 11-74 Men:Women ratio: 1:1.3; 1:2.4 Myasthenia gravis severities were similar Inclusion: Myasthenia gravis Exclusion: Not reported	Robotic Thoracoscopic 42 mos	*Outcome: Robotic; Thoracoscopic* Operating time: 187±48 mins; 198±48 mins Conversion to sternotomy: 1; 1 Postoperative morbidity: 2.7%; 2.5% No mortality at 30-days Bleeding incidence and phrenic nerve resections were similar Histologic findings were similar with exception of follicular hyperplasia, which was more prevalent in thoracoscopic group (45% vs. 68%)	Fair Retrospective; noncontemporaneous controls; limited patient characteristics; statistical analyses not reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
					Complete remission at follow-up: 39.3%; 20.3% (*P*=0.01)	
Cakar 2007	Retrospective cohort with historic controls (10 sternotomy procedures followed by 9 robotic over 10-year time frame)	19 Robotic, 9 Open, 10	Age, sex distribution, BMI, ASA score, myasthenia gravis classification were similar (data not shown) Inclusion: Thymectomy for myasthenia gravis Exclusion: Not reported	Robotic Open 12 mos	*Outcome: Robotic; Open* Operating time: 154 min, range 94-312; 110 mins, range 42-152 (*P*<0.05) HLOS: 5 days; 10 days (*P*<0.05) Postoperative complications: 1; 3 Reoperation: 0; 2 Follow-up: 13±10 mos; 74±23 mos Thymoma: 44%; 30% Disease improvement at follow-up: 9/9; 8/10 There were no major complications and blood loss was <50 mL in all cases There were no conversions to open	Poor Financial disclosure not reported Retrospective; small sample size; noncontemporaneous controls; patient characteristic data were not shown; statistical significance of data not always reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
					surgery	

Thyroidectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Lang 2011	Retrospective cohort	46 Robotic, 7 Endoscopic, 39	*Robotic; Endoscopic* Mean age: 43.4 yrs, range 20.2-54.7; 44.4 yrs, range 20.3-58.3 (NS) Men/Women: 0/7; 1/38 (NS) Size of largest nodule: 1.6 cm, range 0.5-3; 2.5 cm, range 0.8-3.5 (NS) Inclusion: <60 yrs of age; benign nodule <4 cm or malignant nodule <2 cm Exclusion: Not reported	Robotic Endoscopic 6 mos	*Outcome: Robotic, Endoscopic* Operating time: 149 mins, range 92-190; 100 mins, range 50-220 (*P*=0.018) Time for first 7 cases: 149 mins, range 92-190; 120 mins, range 95-220 (*P*=0.004) Conversions to open procedure: 0; 1 (NS) Blood loss: 30 mL, range 20-60; 20 mL, range 10-60 (NS) Weight of excised thyroid: 11.3 g, range 6-67.1; 19 g, range 10.7-37 (*P*=0.021) HLOS: 2 days; 2 days (NS) Pain score day 0: 4; 2 (*P*=0.025) Pain score day 1: 2; 2 (NS)	Poor Retrospective, small sample size; patients chose surgical method; robotic group had significantly fewer patients; robotic group composed of first patients to be treated with robotic surgery at institution

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
					Extent of resection, final pathology, and surgical complications were similar Robotic surgery cost approximately $1300 more than endoscopic surgery (details not provided)	
Lee 2011c	Retrospective cohort	411 Robotic, 174 Open, 237	*Robotic; Open* Mean age: 39.9±8.8 yrs; 51.1±11.1 yrs (*P*<0.001) Women: 88.5%; 78.9% (*P*=0.012) BMI: 22.9 kg/m2; 23.9 kg/m2 (*P*<0.001) Inclusion: Total thyroidectomy with central node dissection; papillary thyroid carcinoma;	Robotic Open No follow-up	*Outcome: Robotic; Open* *Radioablation sessions: 1.95±0.49; 2.05±0.51 (*P*=0.05) * Mean total RAI ablation dose (mCi): 62.2±19.1; 66.8±27.3 (NS) * Measures of surgical completeness Matched pairs had similar clinical parameters of surgical completeness (thyroid bed-to-background ratio of radioactive iodine	Fair Financial disclosure not reported Retrospective; robotic group was younger, had more women, had lower BMI, and had less advanced disease; perioperative data not

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
			radioactive iodine ablation Exclusion: Not reported Operative findings: Tumor size, prevalence of multifocality, lymph node metastasis, and T-stage were similar. Robotic group more likely to be stage I disease and open group more likely to have stage III disease (*P*<0.001). Authors also generated subgroup of matched cases		uptake, thyroglobulin levels on first radioactive iodine scan, and total number of ablation sessions or dose needed to ablate remnant thyroid)	reported

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			(108 pairs) based upon propensity scores derived from 8 criteria (3 demographic and 5 pathologic)			
Kim 2011b	Retrospective cohort	302 Robotic, 69 Endoscopic, 95 Open, 138	*Robotic; Endoscopic; Open* Mean age: 41.3±7.8 yrs; 39.9±9.1 yrs; 51.8±8.9 yrs (Open group older, *P*<0.001) Men/Women: 6/63; 2/93; 34/104 (Robotic vs. Open, *P*=0.005) BMI: 22.7 kg/m2; 22.7 kg/m2; 24.4 kg/m2 (Robotic	Robotic Endoscopic Open No follow-up	*Outcome: Robotic; Endoscopic; Open* Operating time: 3:16±0:45 hrs; 2:16±0:31 hrs; 1:21±0:16 hrs (all analyses *P*<0.001) Tumor size: 0.6±0.2 cm; 0.6±0.2 cm; 0.7±0.2 cm (Open group vs. other groups, *P*=0.038) HLOS: 3.1±0.7 days; 3.1±0.9 days; 2.8±0.9 days (NS) Number of retrieved nodes and metastatic nodes was similar There were no conversions to open	Poor Financial disclosure not reported Retrospective; criteria for determining surgical method were not reported; Significant differences in patient age, sex ratio, and BMI between robotic and

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			vs. Open, *P*<0.001) Inclusion: Total thyroidectomy and ipsilateral central lymph node dissection; <1 cm papillary thyroid carcinoma Exclusion: Lobectomies; poorly differentiated cancer; bilateral lymph node dissection; distant metastasis; invasion to adjacent organs Patients with severe thyroiditis was		surgery Complications were similar	open groups; thyroiditis more likely in open group; data on complications was obtained via telephone interview of patients; no follow-up

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			relative contraindication for robotic or endoscopic surgery.			
Lee 2011b	Retrospective cohort	259 Robotic, 163 Endoscopic, 96	Robotic; Endoscopic Mean age: 38.7±8.2 yrs; 39.9±6.5 yrs (NS) Men/Women: 6/157; 2/94 BMI: 22.9 kg/m^2; 23 kg/m^2 (NS) Bilateral total thyroidectomy: 29.4%; 2.1% (global *P*<0.001 No lymph node dissection: 6.8%, 45.8% (global *P*<0.001*)* Operative findings: Benign lesions: 6.7%; 42.7%	Robotic Endoscopic Min 3 mos	*Outcome: Robotic; Endoscopic* Operating time: 110.1±50.7 mins; 142.7±52.1 mins (*P*=0.041) Blood loss: 4.5±3.8 mL; 5.1±3 mL (NS) HLOS: 2.8 days; 3.2 days (NS) Postoperative complications: 11%; 10.4% (NS) HLOS: 3.2±1.9 days; 2.8±1.1 days (NS) Learning curve was less steep for robotic procedure. Dissected lymph nodes: 4.5±1.5; 2.4±1.9 (*P*=0.004)	Poor Financial disclosure not reported Retrospective; robotic group had more severe disease than endoscopic group; authors did not discuss whether 6-12 months was sufficient follow-up to determine recurrence rates or how

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
			(*P*<0.001) Pathology measures were similar except for significantly greater presence of adenomatous hyperplasia in endoscopy group Inclusion: Follicular neoplasm tumor ≤5 cm; differentiated thyroid carcinoma tumor ≤2 cm Exclusion: Previous neck surgery; severe Graves' disease; malignancy with extrathyroid		There were no conversions to open procedure At 3-6 mos follow-up, serum thyroglobulin and antithyroglobulin antibody levels were similar; At 6-12 mos, there was no tumor recurrence. Operating time steady state achieved after 35-40 cases of robotic and 55-60 cases of endoscopic thyroidectomy.	many patients were followed this long.

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
			invasion or distant metastasis; lesion in dorsal thyroid			
Lee 2010	Prospective cohort	84 Robotic, 41 Open, 43	Robotic; Open Mean age: 39±7 yrs; 37.7±6.5 yrs (NS) Men/Women: 3/38; 3/40 (NS) Inclusion: Follicular thyroid carcinoma ≤4 cm; papillary thyroid carcinoma ≤2 cm Exclusion: Previous neck surgery; 21-65 yrs of age; vocal fold paralysis; voice or laryngeal	Robotic Open 3 mos	*Outcome: Robotic; Open* Operating time: 128.6±36.3 mins; 98±22.2 mins (*P*=0.001) Blood loss: 3.5±3 mL; 4.9±3.6 mL (P=0.54) HLOS: 2.5 days; 3.2 days (NS) Hyperesthesia or paresthesia of neck at 1 wk: 36.6%; 95.3% (*P*=0.01) and at 3 mos: 9.8%; 65.1% (*P*=0.002) Complications were similar Analgesic use and pain scores were similar Patients in robotic group Swallowing impairment index at 1 wk: 7.2±2.9;	Poor Small sample size; patients chose surgical method

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
			disease requiring therapy; malignancy with extrathyroid invasion; distant metastasis; lesion in dorsal thyroid Tumor characteristics: Multiplicity, bilaterality, tumor size and stage, and number of metastatic lymph nodes were similar		14.1±5.4 (*P*=0.001) and at 3 mos: 4.7±2.2; 9.3±4.6 (*P*=0.007) Voice handicap index was similar at all times	

Trachelectomy

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**Outcomes Assessed Main Findings**	**Quality Comments**
Nick 2012	Retrospective cohort	37 Robotic, 12 Open, 25	Robotic; Open Mean age: 29.8 yrs, range 25.3-33.3; 28.7 yrs, range 21.4-37.2 (NS) Parity, Tumor stage, Tumor histology were similar (NS) Inclusion: Early stage cervical Ca with desire for fertility Exclusion: NR	Robotic Open Median follow-up 17.0 months (range 0.30-64.9 months)	Outcome: Robotic; Open Operating time: 294 mins, range 207-379; 328 mins, range 203-392 (NS); Blood loss: 62.5 mL, range 25-450; 300 mL, range 50-1100 (*P*=0.0001) HLOS: 1 day range 1-2; 4 range 3-9 (*P*<0.001); Transfusion rate similar (NS); Rate of conversion to hysterectomy: 4 (33%); 1 (4%) (p=0.03) Morbidity <30 days similar for fever, UTI, and retention (NS); Morbidity >30 days overall: 1 (13%); 14 (58%) (p=0.07)	Good Retrospective; small sample size; Authors conclusion: Reduced blood loss, and LOS but concerned with high conversion rate to hysterectomy in fertility seeking women

Vesico-vaginal Fistula

Individual studies						
Reference	**Study Design**	**Sample size**	**Patient Characteristics**	**Intervention Comparator Follow-up**	**<u>Outcomes Assessed</u> Main Findings**	**Quality Comments**
Gupta 2010	Retrospective cohort with matched controls	32 Robotic, 12 Open, 20	Robotic; Open Mean age: 27.1 yrs, range 16-46; 27.5 yrs, range 18-44 (NS) Parity, previous delivery location, cause of fistula, history of surgical repair, and fistula size were similar Inclusion: Recurrent vesico-vaginal fistula Exclusion: Not reported	Robotic Open No follow-up	Outcome: Robotic; Open Operating time: 140 mins, range 110-180; 148.5 mins, range 100-210 (NS) Blood loss: 88 mL, range 50-200; 170 mL, range 110-400 (P<0.05) HLOS: 3.1 days; 5.6 days (P<0.05) Complications: 0; 2 (NS) Success: 100%; 90% (NS)	Poor Retrospective; small sample size; matching process and criteria unclear

Appendix F. Guideline Summary Table

Recommending Body, Year Published	Recommendation(s)[6]	Evidence Base Quality
American Urological Association (2010) *Guideline on the Management of Benign Prostatic Hyperplasia (BPH)*	*Surgical Procedures* *Laparoscopic and Robotic Prostatectomy p.22* Option: Men with moderate to severe LUTS and/or who are significantly bothered by these symptoms can consider a **laparoscopic or robotic prostatectomy**. There are insufficient published data on which to base a treatment recommendation. [Based on review of the data and Panel consensus.]	*Systematic review* **Poor**
European Association of Urology (2011) *Guidelines on Bladder Cancer Muscle-invasive and Metastatic*	*7.5 Conclusions on urinary diversion after radical cystectomy p.31* **Laparoscopic and robotic-assisted laparoscopic cystectomy** is feasible but still investigational. Level of Evidence: 3 [Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports] *7.6.1 Recommendations for radical cystectomy* **Laparoscopic and robotic-assisted laparoscopic cystectomy** may be options. However, current data have not sufficiently proven the advantages or disadvantages of laparoscopic cystectomy. Grade: C [Made despite the absence of directly applicable clinical studies of good quality]	*Systematic review* **Fair**
NCCN (2011) *Esophageal and esophagogastric junction cancers*	*Principles of Surgery p.26* Acceptable operative approaches for resectable esophageal and esophagogastric junction cancer: • **Robotic minimally invasive esophagogastectomy**	*Systematic review* **Fair**
NCCN (2012) *Kidney cancer*	*Principles of Surgery p.9* **Open, laparoscopic, or robotic surgical techniques** may be used to perform radical and partial nephrectomies. Grade: Category 2A [Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.]	*Systematic review* **Fair**
NCCN (2012) *Prostate Cancer*	*Principles of Surgery p.17* Pelvic Lymph Node Dissection (PLND): can be performed using an open, **laparoscopic or robotic technique**. Grade: Category 2A [Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.]	*Systematic review* **Fair**

[6] The information provided is not meant to describe indications for surgery. It simply notes references to robotic surgery in coordination with guideline recommendations.

Recommending Body, Year Published	Recommendation(s)[6]	Evidence Base Quality
	Radical Prostatectomy: **Laparoscopic & robotic-assisted radical prostatectomy** are used commonly. In experienced hands, the results of these approaches appear comparable to open surgical approaches.	
NICE (2008) *Totally endoscopic robotically assisted coronary artery bypass grafting*	*1 Guidance p.1* 1.1 Current evidence on the safety and efficacy of **totally endoscopic robotically assisted coronary artery bypass grafting** does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake **totally endoscopic robotically assisted coronary artery bypass grafting** should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the public* is recommended. • Enter all patients having totally endoscopic robotically assisted coronary artery bypass grafting onto the UK Central Cardiac Audit Database.	*Systematic review* **Fair**
NICE (2008) *Laparoscopic prostatectomy for benign prostatic obstruction*	*1 Guidance p.1* 1.1 Current evidence on the safety and efficacy of laparoscopic prostatectomy for benign prostatic obstruction (BPO) is inadequate in both quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake laparoscopic prostatectomy for BPO should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy, make them aware of alternative treatment options and provide them with clear written information. 1.3 This procedure should only be carried out by surgeons with special training and experience in laparoscopic radical prostatectomy. 1.4 Patients should only be offered this procedure if they would otherwise be considered for open prostatectomy, rather than transurethral resection, for BPO. *2.2 Outline of the procedure* 2.2.1 **Laparoscopic prostatectomy is performed with the patient under general anaesthesia, using either a transperitoneal or an extraperitoneal approach, with or without computer (robotic) assistance**.	*Systematic review* **Fair**
NICE (2008) *Prostate cancer: diagnosis and*	*4.4 Initial Treatment Options p.24* The treatment options for men with localised prostate cancer are:	*Systematic review*

Recommending Body, Year Published	Recommendation(s)[6]	Evidence Base Quality
treatment	• **Radical prostatectomy (open, laparoscopic or robotically assisted laparoscopic)** *Recommendations p.27* • Healthcare professionals should offer radical prostatectomy or radical radiotherapy (conformal) to men with intermediate-risk localised prostate cancer. • Healthcare professionals should offer radical prostatectomy or radical radiotherapy (conformal) to men with high-risk localised prostate cancer where there is a realistic prospect of long-term disease control. Qualifying statement: There is no strong evidence for the benefit of one treatment over another. Relatively little health gain is required for these interventions to become demonstrably cost-effective.	**Good**
NICE (2009) *Endopyelotomy for pelviureteric junction obstruction*	*1 Guidance p.1* 1.1 Current evidence shows that endopyelotomy for pelviureteric junction (PUJ) obstruction is efficacious in the short and medium term although there is a risk of obstruction recurrence in the long term. The evidence on safety raises no major concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 This procedure should be carried out only in units with specific expertise in endopyelotomy for PUJ obstruction, by specialist teams who can offer a range of procedures including laparoscopic pyeloplasty. *2 The procedure* 2.1 Indications and current treatments 2.1.2 Conservative treatment may include long-term use of low-dose antibiotics. Current surgical options to reconstruct and normalise the anatomy of the PUJ include **open or laparoscopic pyeloplasty (with or without robotic assistance)** and electrocautery cutting balloon treatment.	*Systematic review* **Fair**
NICE (2009) *Laparoscopic cystectomy*	*1 Guidance p.1* 1.1 Current evidence on the safety and efficacy of laparoscopic cystectomy appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patient selection for laparoscopic cystectomy should involve a multidisciplinary team experienced in the management of bladder cancer. 1.3 Clinicians undertaking laparoscopic cystectomy should have special training. The British Association of Urological Surgeons (BAUS) has produced training standards. 1.4 Clinicians should submit data on all patients undergoing this procedure to the BAUS Cancer Registry & Sections Audit with a view to further publication on long-term survival outcomes. *2.2 Outline of the procedure*	*Systematic review* **Fair**

Recommending Body, Year Published	Recommendation(s)[6]	Evidence Base Quality
	2.2.4 There are various ways of carrying out **laparoscopic cystectomy and the procedure may be performed with computer (robotic) assistance**.	
NICE (2006) *Laparoscopic radical prostatectomy*	*2.2 Outline of the procedure p.1* 2.2.1 A laparoscope and trocars are inserted through small incisions in the abdominal wall. The approach can be either transperitoneal or extraperitoneal. The prostate, adjacent tissue and lymph nodes are dissected and removed, and the urethra, which is cut during the procedure, is reconnected. Lymph nodes can be removed during the procedure for histological examination before removing the prostate. **Robotically assisted laparoscopic prostatectomy** is a development of this procedure but it is not yet clear whether there is any advantage over conventional laparoscopy.	*Systematic review* **Fair**
Society of American Gastrointestinal and Endoscopic Surgeons (2011) *Surgical Treatment of Esophageal Achalasia*	*Types of surgical approach: Recommendations p.9* Compared with laparoscopy, **robotic assistance** has been demonstrated to decrease the rate of intraoperative esophageal mucosal perforations (++, weak), but no clear differences in postoperative morbidity, symptom relief, or long-term outcomes have been described. Further study is necessary to better establish the role of **robotic myotomy**. ++ = low quality of evidence	*Systematic review* **Fair**
Society of American Gastrointestinal and Endoscopic Surgeons (2010) *Surgical Treatment of Gastroesophageal Reflux Disease*	*Use of robotic surgery p.11* While **robotic assistance** can be safely and effectively used for fundoplication, its higher cost compared with conventional laparoscopy and similar short-term patient outcomes make it a less than ideal initial choice (Grade B). Nevertheless, further study regarding learning curves and surgeon workload with the **robotic technique** are needed before stronger recommendations can be made. Grade: B [Based on high level, well-performed studies with varying interpretations and conclusions by the expert panels]	*Systematic review* **Fair**
Spanish NHS (2008) *Clinical Practice Guideline for Prostate Cancer Treatment*	*5.3 Surgery – Questions to answer p.40* • In patients with clinically localised prostate cancer for which surgery is indicated, what is the safety and efficacy of different types of **laparoscopic radical surgery (transperitoneal or extraperitoneal, robotic-assisted or not)** in comparison with open radical prostatectomy? *Recommendation p.45* In clinically localised prostate cancer with radical prostatectomy indicated, either laparoscopic or open surgery can be employed. Grade B [A body of evidence consisting mainly of studies rated as 2++, directly applicable to the target population of the guideline, which demonstrate overall consistency of results; or evidence extrapolated from	*Systematic review* **Good**

Recommending Body, Year Published	Recommendation(s)[6]	Evidence Base Quality
	studies rated as 1++ or 1+.]	

***Individual Guideline Rating Keys**

Appendix G. Quality Assessment of Selected Guidelines

Criteria	Guideline Developer, Year													
	NCCN, 2011	NCCN, 2012a	NCCN, 2012b	NICE, 2008a	NICE, 2008b	NICE, 2006	NICE, 2009a	NICE, 2009b	NICE, 2008c (full guideline)	SAGES, 2011	SAGES, 2010	AUA, 2010	EAU, 2011	Spanish NHS, 2008
Section 1: Primary Criteria														
Rigor of Development: Evidence	Fair	Fair	Fair	Fair	Fair	Fair	Fair	Fair	Good	Good	Good	Poor[7]	Fair	Good
Rigor of Development: Recommendations	Fair	Fair	Fair	Fair	Fair	Fair	Fair	Fair	Good	Fair	Fair	Good	Fair	Fair[8]
Editorial Independence	Fair	Fair	Fair	Good	Good	Good	Good	Good	Good	Good	N/A	Good	Good	Good
Section 2: Secondary Criteria														
Scope and Purpose	Good	Good	Good	Good	Good	Good	Good	Good	Good	Fair	Fair	Good	Fair	Good
Stakeholder Involvement	Poor	Poor	Poor	Good	Good	Good	Good	Good	Good	Poor	Fair	Fair	Fair	Fair
Clarity and Presentation	Good	Good	Good	Good	Good	Good	Good	Good	Good	Fair	Fair	Fair	Good	Good
Applicability	Good	Good	Good	Fair	Fair	Fair	Fair	Fair	Fair	Poor	Poor	Poor	Poor	Fair
Section 3: Overall Assessment of the Guideline														
How well done is this guideline?	**Fair**	**Fair**	**Fair**	**Fair**	**Fair**	**Fair**	**Fair**	**Fair**	**Good**	**Fair**	**Fair**	**Poor**	**Fair**	**Good**

[7] Rated poor because quality of individual studies and overall strength of the evidence were not assessed. Other elements of the guideline were mostly good to fair.
[8] Rigor of development: Recommendations received a Fair rating because risk of bias was assessed and included using a rating system but not described or discussed in the text.

Appendix H. Quality Assessment Tools

MED PROJECT	Methodology Checklist: Systematic Reviews and Meta-analyses

Study citation (*Include last name of first author, title, year of publication, journal title, pages*)

MED Topic:	key question No.(s):
Checklist completed by:	Date:

SECTION 1: INTERNAL VALIDITY

	In a well conducted systematic review	***In this study the criterion is met:***			
1.1	The study addresses an appropriate and clearly focused question.	YES	NO	UNCLEAR	N/A
1.2	An adequate description of the methodology used is included, and the methods used are appropriate to the question.	YES	NO	UNCLEAR	N/A
1.3	The literature search is sufficiently rigorous to identify all the relevant studies.	YES	NO	UNCLEAR	N/A
1.4	The criteria used to select articles for inclusion is appropriate.	YES	NO	UNCLEAR	N/A
1.5	Study quality is assessed and taken into account.	YES	NO	UNCLEAR	N/A
1.6	There are enough similarities between the studies selected to make combining them reasonable.	YES	NO	UNCLEAR	N/A
1.7	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
1.8	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1	How well was the study done to minimize bias? *Code: Good, Fair or Poor*	GOOD	FAIR	POOR

2.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?				
2.3	Are the results of this study directly applicable to the patient group targeted by this key question?	YES	NO	UNCLEAR	N/A
2.4	Other reviewer comments:				

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	Methodology Checklist: Randomized Controlled Trials

Study identification (*Include author, title, year of publication, journal title, pages*)

MED topic:	key question No(s):

Checklist completed by:	Date:

SECTION 1: INTERNAL VALIDITY

	In a well conducted RCT study…	***In this study this criterion is met:***
RANDOM ALLOCATION OF SUBJECTS		
1.1	An appropriate method of randomization was used to allocate participants to intervention groups.	YES NO UNCLEAR N/A
1.2	An adequate concealment method was used such that investigators, clinicians, and participants could not influence enrolment or intervention allocation.	YES NO UNCLEAR N/A
1.3	The intervention and control groups are similar at the start of the trial. (The only difference between groups is the treatment under investigation.)	YES NO UNCLEAR N/A
ASSESSMENT AND FOLLOW-UP		
1.4	Investigators, participants, and clinicians were kept 'blind' about treatment allocation and other important confounding/prognostic factors. If the answer is no, describe any bias that might have occurred.	YES NO UNCLEAR N/A
1.5	The intervention and control groups received the same care apart from the intervention(s) studied.	YES NO UNCLEAR N/A
1.6	The study had an appropriate length of follow-up.	YES NO UNCLEAR N/A
1.7	All groups were followed up for an equal length of time (or the analysis was adjusted to allow for differences in length of follow-up).	YES NO UNCLEAR N/A

1.8	What percentage of the individuals or clusters recruited into each group of the study dropped out before the study was completed? What percentage did not complete the intervention(s)?	
1.9	All the subjects were analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)	YES NO UNCLEAR N/A
ASSESSMENT AND FOLLOW-UP, Cont.		
1.10	All relevant outcomes are measured in a standard, valid and reliable way.	YES NO UNCLEAR N/A
1.11	The study reported only on surrogate outcomes. (If so, please comment on the strength of the evidence associating the surrogate with the important clinical outcome for this topic.)	YES NO UNCLEAR N/A
1.12	The study uses a composite (vs. single) outcome as the primary outcome. If so, please comment on the appropriateness of the composite and whether any single outcome strongly influenced the composite.	YES NO UNCLEAR N/A
CONFLICT OF INTEREST		
1.13	Competing interests of members have been recorded and addressed.	YES NO UNCLEAR N/A
1.14	Views of funding body have not influenced the content of the study.	YES NO UNCLEAR N/A
Section 2: Overall Study Assessment		
2.1	How well was the study done to minimize bias? *Code Good, Fair, or Poor*	GOOD FAIR POOR
2.2	If coded as Fair or Poor what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO UNCLEAR N/A
2.4	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	Methodology Checklist: Cohort Studies

Study identification (*Include author, title, year of publication, journal title, pages*)

Review topic:	key question No.(s), if applicable:
Checklist completed by:	Date:

SECTION 1: INTERNAL VALIDITY

In a well conducted cohort study:		***In this study the criterion is:***
1.1	The study addresses an appropriate and clearly focused question.	YES NO N/A
SELECTION OF SUBJECTS		
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	YES NO N/A
1.3	The study indicates how many of the people asked to take part did so, in each of the groups being studied.	YES NO N/A
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	YES NO N/A
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed?	
1.6	Comparison is made between full participants and those who dropped out or were lost to follow up, by exposure status.	YES NO N/A
ASSESSMENT AND FOLLOW-UP		
1.7	The study employed a precise definition of outcome(s) appropriate to the key question(s).	YES NO N/A
1.8	The assessment of outcome(s) is made blind to exposure status.	YES NO N/A
1.9	Where outcome assessment blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	YES NO N/A

1.10	The measure of assessment of exposure is reliable.	YES NO N/A
1.11	Exposure level or prognostic factor is assessed more than once.	YES NO N/A
1.12	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	YES NO N/A
1.13	The study had an appropriate length of follow-up.	YES NO N/A
1.14	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	YES NO N/A
CONFOUNDING		
1.15	The main potential confounders are identified and taken into account in the design and analysis.	YES NO N/A
STATISTICAL ANALYSIS		
1.16	Have confidence intervals been provided?	YES NO N/A
CONFLICT OF INTEREST		
1.17	Competing interests of members have been recorded and addressed.	YES NO N/A
1.18	Views of funding body have not influenced the content of the study.	YES NO N/A
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimize the risk of bias or confounding, and to establish a causal relationship between exposure and effect? *Code Good, Fair, or Poor*	GOOD FAIR POOR
2.2	If coded as Fair, or Poor what is the likely direction in which bias might affect the study results?	
2.3	Are the results of this study directly applicable to the patient group targeted by this topic?	YES NO N/A
2.4	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated?	YES NO N/A
2.5	Other reviewer comments:	

MED Project 2009. Adapted from NICE and SIGN materials.

MED PROJECT	Methodology Checklist: Economic Evaluation

Study citation (*Include last name of first author, title, year of publication, journal title, pages*)

MED Topic:	key question No.(s):
Checklist completed by:	Date:

Cost
Cost analysis (no measure of benefits)

Economic Evaluations (please circle):

Study Type	*Measurement of Benefits*
Cost minimization	Benefits found to be equivalent
Cost effectiveness analysis	Natural units (e.g., life years gained)
Cost utility analysis	Healthy years (e.g. quality adjusted life years, health years equivalent)
Cost-benefit analysis	Monetary terms

Section 1: applicability

In a well conducted economic study…		*In this study the criterion is met:*
1.1	The results of this study are directly applicable to the patient group targeted by this key question.	YES NO UNCLEAR N/A
If criterion 1.1 is rated no, the study should be excluded.		
1.2	The healthcare system in which the study was conducted is sufficiently similar to the system of interest in the topic key question(s).	YES NO UNCLEAR N/A

SECTION 2: Study Design, Data Collection, and Analysis

In a well conducted economic study…		*In this study the criterion is met:*
2.1	The research question is well described.	YES NO UNCLEAR N/A

2.2	The economic importance of the research question is stated.	YES	NO	UNCLEAR	N/A
2.3	The perspective(s) of the analysis are clearly stated and justified (e.g. healthcare system, society, provider institution, professional organization, patient group).	YES	NO	UNCLEAR	N/A
2.4	The form of economic evaluation is stated and justified in relation to the questions addressed.	YES	NO	UNCLEAR	N/A
Methods to estimate the effectiveness of the intervention					
2.5	*Circle one* a. Details of the methods of synthesis or meta-analysis of estimates are given (if based on a synthesis of a number of effectiveness studies). b. Details of the design and results of effectiveness study are given (if based on a single study).	YES	NO	UNCLEAR	N/A
2.6	Estimates of effectiveness are used appropriately.	YES	NO	UNCLEAR	N/A
2.7	Methods to value health states and other benefits are stated.	YES	NO	UNCLEAR	N/A
2.8	Outcomes are used appropriately.	YES	NO	UNCLEAR	N/A
2.9	The primary outcome measure for the economic evaluation is clearly stated.	YES	NO	UNCLEAR	N/A
2.10	Details of the subjects from whom valuations were obtained are given.	YES	NO	UNCLEAR	N/A
2.11	Competing alternatives are clearly described.	YES	NO	UNCLEAR	N/A
Methods to estimate the costs of the intervention					
2.12	All important and relevant costs for each alternative are identified.	YES	NO	UNCLEAR	N/A
2.13	Methods for the estimation of quantities and unit costs are described.	YES	NO	UNCLEAR	N/A
2.14	Quantities of resource use are reported separately from their unit costs.	YES	NO	UNCLEAR	N/A
2.15	Productivity changes (if included) are reported separately.	YES	NO	UNCLEAR	N/A

2.16	The choice of model used and the key parameters on which it is based are justified.	YES	NO	UNCLEAR	N/A
2.17	All costs are measured appropriately in physical units.	YES	NO	UNCLEAR	N/A
2.18	Costs are valued appropriately.	YES	NO	UNCLEAR	N/A
2.19	Outcomes are valued appropriately.	YES	NO	UNCLEAR	N/A
2.20	The time horizon is sufficiently long enough to reflect all important differences in costs and outcomes.	YES	NO	UNCLEAR	N/A
2.21	The discount rate(s) is stated.	YES	NO	UNCLEAR	N/A
2.22	An explanation is given if costs and benefits are not discounted.	YES	NO	UNCLEAR	N/A
2.23	The choice of discount rate(s) is justified.	YES	NO	UNCLEAR	N/A
2.24	All future costs and outcomes are discounted appropriately.	YES	NO	UNCLEAR	N/A
2.25	Details of currency of price adjustments for inflation or currency conversion are given.	YES	NO	UNCLEAR	N/A
2.26	Incremental analysis is reported or it can be calculated from the data.	YES	NO	UNCLEAR	N/A
2.27	Details of the statistical tests and confidence intervals are given for stochastic data.	YES	NO	UNCLEAR	N/A
2.28	Major outcomes are presented in a disaggregated as well as aggregated form.	YES	NO	UNCLEAR	N/A
2.29	Conclusions follow from the data reported.	YES	NO	UNCLEAR	N/A
2.30	Conclusions are accompanied by the appropriate caveats.	YES	NO	UNCLEAR	N/A

SECTION 3: sensitivity Analysis	
In a well conducted economic study…	*In this study the criterion is met:*

3.1	The approach to sensitivity analysis is given.	YES	NO	UNCLEAR	N/A
3.2	All important and relevant costs for each alternative are identified.	YES	NO	UNCLEAR	N/A
3.3	An incremental analysis of costs and outcomes of alternatives is performed.	YES	NO	UNCLEAR	N/A
3.4	The choice of variables for sensitivity analysis is justified.	YES	NO	UNCLEAR	N/A
3.5	All important variables, whose values are uncertain, are appropriately subjected to sensitivity analysis.	YES	NO	UNCLEAR	N/A
3.6	The ranges over which the variables are varied are justified.	YES	NO	UNCLEAR	N/A
SECTION 4: CONFLICT OF INTEREST					
In a well conducted economic study…		*In this study the criterion is met:*			
4.1	Competing interests of members have been recorded and addressed.	YES	NO	UNCLEAR	N/A
4.2	Views of funding body have not influenced the content of the study.	YES	NO	UNCLEAR	N/A
SECTION 5: OVERALL ASSESSMENT					
5.1	**How well was the study done to minimize bias?** ***Code: Good, Fair or Poor***	GOOD	FAIR	POOR	
5.2	If coded as fair or poor, what is the likely direction in which bias might affect the study results?				
5.3	Other reviewer comments:				

MED Project 2011. Adapted from BMJ, NICE, and the Consensus on Health Economic Criteria (CHEC).

MED PROJECT	Methodology Checklist: Guidelines

Guideline citation *(Include name of organization, title, year of publication, journal title, pages)*

MED Topic:	key question No.(s), if applicable:
Checklist completed by:	Date:

SECTION 1: PRIMARY CRITERIA

	To what extent is there	***Assessment/Comments:***
1.1	**RIGOR OF DEVELOPMENT: Evidence** • Systematic literature search • Study selection criteria clearly described • Quality of individual studies and overall strength of the evidence assessed • Explicit link between evidence & recommendations *(If any of the above are missing, rate as poor)*	GOOD FAIR POOR
1.2	**RIGOR OF DEVELOPMENT: Recommendations** • Methods for developing recommendations clearly described • Strengths and limitations of evidence clearly described • Benefits/side effects/risks considered • External review	GOOD FAIR POOR
1.3	**EDITORIAL INDEPENDENCE**[9] • Views of funding body have not influenced the content of the guideline • Competing interests of members have been recorded and addressed	GOOD FAIR POOR

If any of three primary criteria are rated poor, the entire guideline should be rated poor.

SECTION 2: SECONDARY CRITERIA

2.1	**SCOPE AND PURPOSE** • Objectives described • Health question(s) specifically described • Population (patients, public, etc.) specified	GOOD FAIR POOR

9 Editorial Independence is a critical domain. However, it is often very poorly reported in guidelines. The assessor should not rate the domain, but write "unable to assess" in the comment section. If the editorial independence is rated as "poor", indicating a high likelihood of bias, the entire guideline should be assessed as poor.

SECTION 2: SECONDARY CRITERIA, CONT.				
2.2	**STAKEHOLDER INVOLVEMENT** • Relevant professional groups represented • Views and preferences of target population sought • Target users defined	GOOD	FAIR	POOR
2.3	**CLARITY AND PRESENTATION** • Recommendations specific, unambiguous • Management options clearly presented • Key recommendations identifiable • Application tools available Updating procedure specified	GOOD	FAIR	POOR
2.4	**APPLICABILITY** • Provides advice and/or tools on how the recommendation(s) can be put into practice • Description of facilitators and barriers to its application • Potential resource implications considered Monitoring/audit/review criteria presented	GOOD	FAIR	POOR
SECTION 3: OVERALL ASSESSMENT OF THE GUIDELINE				
3.1	How well done is this guideline?	GOOD	FAIR	POOR
3.2	Other reviewer comments:			

[This tool is adapted from the Appraisal of Guidelines Research & Evaluation (AGREE) II tool. The full AGREE II tool is available from http://www.agreetrust.org/resource-centre/agree-ii/]

Description of Ratings: Methodology Checklist for Guidelines

The checklist for rating guidelines is organized to emphasize the use of evidence in developing guidelines and the philosophy that "evidence is global, guidelines are local." This philosophy recognizes the unique situations (e.g., differences in resources, populations) that different organizations may face in developing guidelines for their constituents. The second area of emphasis is transparency. Guideline developers should be clear about how they arrived at a recommendation and to what extent there was potential for bias in their recommendations. For these reasons, rating descriptions are only provided for the primary criteria in section one. There may be variation in how individuals might apply the good, fair, and poor ratings in section two based on their needs, resources, organizations, etc.

Section 1. Primary Criteria (rigor of development and editorial independence) ratings:

Good: All items listed are present, well described, and well executed (e.g., key research references are included for each recommendation).
Fair: All items are present, but may not be well described or well executed.
Poor: One or more items are absent or are poorly conducted

Appendix I. Summary of Federal and Private Payer Policies

Payer	Coverage summary
Medicare Effective: May 2005	CMS Manual System, Medicare Claims Processing, Updated to the Medicare Outpatient Code Editor (May 20, 2005). S2900 added to list of valid codes; S2900 added to list of non-reportable codes.
Medicare LCDs	No local coverage determinations have been issued.
Aetna	No policies identified addressing coverage of robotic assisted surgery.
Regence BCBS Washington	Regence Washington, Reimbursement Policy, Invalid Services "Providers will not be reimbursed nor allowed to retain reimbursement for Invalid services. Invalid services are denied provider write-off. The following are examples of services that Regence considers to be Invalid. This is not an all inclusive list. … • Surgical techniques requiring use of robotic surgical system (S2900 - list separately in addition to code for primary procedure)"
Group Health	No policies identified addressing coverage of robotic assisted surgery.

Appendix J. Public Comments and Disposition

OVERVIEW OF PUBLIC COMMENTS AND DISPOSITION

The Center for Evidence-based Policy is an independent vendor contracted to produce evidence assessment reports for the WA HTA program. For transparency, all comments received during the comments process are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

This document responds to comments from the following parties:

Key Questions

- Phil Colmenares, MD, MPH
- James R. Porter, MD (Swedish Medical Center)
- Andrew Yoo, MD; and Matt Moore, MHA (Ethicon Endo-Surgery, Inc)

Draft Report

- Scott Adams (Pullman Regional Hospital)
- Kristen Austin, MD (Swedish Medical Center)
- Ralph Aye, MD, FACS (Swedish Cancer Institute)
- Michael Blee (Kootenai Health)
- Steven R. Brisbois (Sacred Heart Medical Center)
- D. Mark Brown, MD (Southwestern Washington Urology Clinic)
- Michael F. Burke, MD, FACS (Valley Medical Center)
- Eve Cunningham
- Paul H. Eun, MD (Dedicated to Women's Health Specialists, Inc)
- Michael Florence, MD, FACS (Swedish Medical Center)
- Joel B. Flugstad, MHPA (Swedish Medical Center)
- Brian Fong, MD, FRCS(C) (Western Washington Medical Group)
- Theresa Froelich, DO (University Place Medical Clinic)

- Heidi J. Gray, MD (University of Washington)
- Peter Grimm, DO (Prostate Cancer Center of Seattle)
- Patti Holten
- Catherine Hunter, DO
- Peggy Hutchison, MD (Seattle OB/GYN Group)
- Intuitive Surgical
- John Paul Isbell, MD
- Frank Kim, MD
- Richard Koehler, MD
- Baiya Krishnadasan, MD, FACS (Franciscan Health System)
- David Kummerlowe (CADRE, Inc.)
- Roque Lanza, MD, FACOG
- Thomas Lendvay, MD, FACS
- John Lenihan Jr., MD (University of Washington School of Medicine)
- Brian E. Louie, MD, FRCSC, FACS (Swedish Cancer Institute and Medical Center)
- John Luber, MD, FACS
- Gordon L. Mathes, Jr., MD (Rocky Mount Urology Associates)
- Patris Marandi, MD (Providence Everett Medical Center)
- Heather Miller, MD (Swedish Medical Center)
- Karen Nelson, MD
- Kerilyn Nobuhara, MD, MHA (Senior Medical Consultant, Washington Health Care Authority)
- Steve Poore, MS, MD, FACOG (Women's Clinic-MultiCare Northshore Clinic)
- James Porter, MD; Todd Strumwasser, MD; and Mary G. Gregg, MD, MHA (Swedish Medical Center)
- Charles Richards, MD (Pullman Regional Hospital)

- Clifford W. Rogers, MD (Minimally-Invasive Gynecologic Surgery)
- Dennis W. Shook
- Leland Siwek, MD (Providence Sacred Heart Medical Center)
- Doug Sutherland, MD (MultiCare Urology)
- Kim Tillemans, DO
- Renata R. Urban, MD (University of Washington Medical Center)

Specific responses pertaining to each comment are included in Table 1 and 2. The full version of each public comment received along with additional resources provided by parties is available in the Public Comments and Responses supplemental document.

Table 1. Response to Public Comments on Key Questions

Reviewer	Comment	Disposition
Phil Colmenares, MD		
	"Robotic Assisted Surgery" is too general. It seems to me that you need to go procedure by procedure. Next comment about KQ1: The function of an HTA program is to deal directly with clinical effectiveness. In looking at the final determinations for Lumbar Fusion and Total Knee Replacement, the WA-HTA addressed clinical effectiveness. You did not "water down" the question by conflating it with clinical efficacy. Clinical efficacy studies will certainly be reviewed, but a formal HTA program should review all data with one focus: To what extent does each study (including clinical efficacy studies) address clinical effectiveness? Clinical efficacy studies need to be reviewed, but the question is about clinical effectiveness. The last part of the question addresses outcomes. I don't know whether the WA-HTA has a hierarchy of outcomes, but I'm not sure that I would lump outcomes such as "complete cancer eradication" with outcomes such as "reduced anesthesia use." I think that patients might differ on the valuation of those two outcomes as well. In addition, you should distinguish between hard clinical outcomes, and other outcomes. As I discuss below with regard to the example of robotic assisted laparoscopic prostatectomy (RALP), the value of the "trifecta" outcome of reduced impotence/incontinence/positive surgical margins is probably exponentially more important to patients than "reduced anesthesia use" or even "reduced hospital stay." All of these are worthy outcomes to consider, but the integrity of a health technology assessment process depends on how well you are able to place each outcome in proper perspective. For the few robotic procedures that do demonstrate evidence of clinical or comparative effectiveness, the next crucial question (which you have unfortunately not even acknowledged) should be the volume of procedures necessary to achieve consistently low levels of complications. This is much different, and a higher (but more patient-	*Thank you for your comments.* *Results will be presented by procedure in the report.* *The report will include assessment of efficacy and effectiveness as available in the evidence.* *Assessment of clinically meaningful outcomes added to key question #1.* *Experience by provider and facility volume were added to key question# 3.*

Reviewer	Comment	Disposition
	oriented outcome) than mere competency in performing the procedure. **Proposed KQ5:** What is the minimum number of robotic surgeries required to attain consistently low levels of the most concerning complications? For example, for robotic prostatectomy, Dr. Patel has called for using a "trifecta" outcome: (1) impotence; (2) incontinence; (3) positive surgical margins. How many robotic prostate surgeries should be expected to consistently achieve the level of expertise necessary to consistently demonstrate low levels of this trifecta outcome? Robotic prostatectomy may be a bad example because it is not clear that patient-oriented outcomes are better with RALP. Therefore, asking the question KQ5 is not even indicated. KQ5 would only be indicated for robotic procedures that demonstrate comparative effectiveness. Nevertheless, this is a crucial question to include. In few other areas of clinical medicine than this new, radical departure from past surgical techniques should **questions of surgical expertise** be an explicit part of the technology assessment. And, specifically, not just competency with the procedure, but, of far more importance to patients, expertise that **consistently** yields the lowest complications and the highest successes. (The numbers for RALP have been as low as 100, but as high as 1,600 to achieve the necessary expertise.) Again, questions of surgical expertise are often mentioned in technology assessments, but in this particular arena I strongly suggest that it needs its own separate question.	
James R Porter, MD (Swedish Medical Center)		
	Key Question 1: there are several studies showing comparative superiority of robotic-assisted surgery over laparoscopic or traditional open surgery. There are few, if any randomized controlled trials comparing robotic-assisted surgery to laparoscopic or open surgery. So most of the information is gained from case series with historical comparisons to open or laparoscopic surgery. ○ It is important to recognize that the experience of robotic assisted prostatectomy is very early and the comparison studies are looking at a very mature open prostatectomy experience in the literature with a very early robotic assisted prostatectomy experience.	*Thank you for your comments.* *All references were forwarded to the TAC.* *Studies provide evidence. No changes to the key questions.*

Reviewer	Comment	Disposition
	○ If the early literature of open prostatectomy (1982 – 1995) is carefully evaluated the complication rates, cancer control rates and morbidity are much greater than what is seen with current assisted prostatectomy series. (1) – publication indicated patients undergoing robotic assisted prostatectomy showed surgical site infection rate as compared to patients undergoing open prostatectomy. ▪ ▪ (2) – study indicated no significant difference and complications between the open prostatectomy patient's compared to the robotic assisted prostatectomy patients. This paper shows equal outcomes with decreased hospital stay and decreased bladder neck contracture rate for the robotic assisted procedures versus open. ▪ (3) – found that robotic-assisted partial nephrectomy was superior to laparoscopic partial nephrectomy with regard to blood loss and length of hospital stay. The major advantage of robotic-assisted partial nephrectomy was a decrease in the warm ischemia time that the kidney was clamped during partial nephrectomy. This significant difference speaks to the improved reconstructive abilities of the robotic platform. This improved warm ischemia time has significant implications for renal function recovery. ▪ (4) – demonstrated superior adjusted perioperative outcomes after robotic assisted prostatectomy as compared to open prostatectomy in virtually all examined outcomes. ▪ key question 4: studies look at operating room costs and do not take into account the cost savings created by shorter length of hospital stay which has been clearly demonstrated in multiple studies of robotic prostatectomy. Another savings which is difficult to measure is the money saved by employers when a patient is able to return to work sooner after robotic surgery as compared to open surgery. The charge to insurance payers for robotic procedures is the same charge as the laparoscopic procedure given the equivalent CPT codes for robotic and laparoscopic surgery. In the state of Washington, there is no additional charge to insurance company's or the state for robotic-assisted procedures. The increased capital costs associated with the robotic surgical systems has been incurred by hospital systems in an effort to provide patients with state of the art surgical care. Cited the following: ○ (1). Publication from the Mayo Clinic in Urology (Urology Oct. 2011; 78(4), pages 827-31. Epub 2011 July 29) ○ (2). Study from the Mayo Clinic published in the British Journal of Urology (BJU Int 2009 Feb; 103(4), pages 448-53. Epub 2008 Sept 3). ○ (3). Article published in the Journal of Urology in 2009 (J Urol 2009 Sept; 182(3), pages 866-72. Epub 2009 July 17). ○ (4). National Inpatient Sample was published in European Urology (Eur Urology: 2011 Dec. 22)	*The report will describe all cost perspectives and model assumptions as described by the identified evidence.*
Andrew Yoo and Matt Moore (Ethicon Endo-Surgery, Inc)		
	Policy Context – Population: the specific pathology and patient populations is important to note when comparing surgical approaches. This not only can profoundly generally effect outcomes but also directly effects the procedure itself. Policy Context – Intervention: Robotic assisted surgery is perhaps more precisely defined as Robotic assisted endoscopic surgery. In the specific anatomic location – robotic assisted laparoscopic surgery and robotic assisted video assisted thoracic surgery (VATS). Policy Context – Comparator: Precisely defining the comparative approach and current	*Thank you for your comments.* *No changes to context, PICO sections, or KQs.* *The report will be organized by procedure.*

Reviewer	Comment	Disposition
	gold standard is of the utmost importance when evaluating the effectiveness of Robotic assisted endoscopic surgery. Policy Context – Outcomes: Note the difference between statistical significance and clinical relevance. Requested three distinct modifications to the draft key questions: ○ The data should compare robot to open *and* traditional minimally invasive procedures versus one *or* the other; ○ That the evidence asked for is segmented by procedure, as the outcomes can greatly vary based on the type of surgery performed; and ○ A broad term such as "traditionally minimally invasive" would be a more inclusive and appropriate terminology. **KQ1:** What is the procedure and indication (e.g. benign vs. malignant disease) specific evidence of the clinical efficacy and effectiveness of robotic assisted surgery compared with open ~~or~~ AND traditionally minimally invasive, i.e., laparoscopic approaches not using robotic assistance? Does robotic assisted surgery improve patient outcomes compared to open AND laparoscopic procedures? Include consideration of short and long-term outcomes including complete cancer eradication, reduced hospital stay, and reduced anesthesia use. **KQ2:** For robotic assisted surgery, what is the procedure and indication specific evidence of the severity and incidence of safety or adverse event concerns compared with open ~~or~~ AND laparoscopic approaches? Include consideration of morbidity, mortality, reoperation, excess bleeding, and extended hospital stay. **KQ3:** What is the evidence that robotic assisted surgery has differential efficacy or safety issues in sub populations compared to open AND laparoscopic procedures? Including consideration of: Gender Age Psychological or psychosocial co-morbidities Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes and high BMI, prior operations, Provider	*No changes to key questions to affect "or"/"and". We do not think this will impact the meaning.* *Terminology change (e.g., traditionally minimally invasive) will not affect the report evidence base.*

Reviewer	Comment	Disposition
	type, setting or other provider characteristics, stage (for malignancy), Payer / beneficiary type including worker's compensation, Medicaid, state employees **KQ4:** What is the evidence of cost and cost-effectiveness of robotic surgery compared with open ~~or~~ AND laparoscopic approaches (or perhaps other well accepted approaches including – vaginal hysterectomy, open appendectomy, open inguinal hernia repair)? This should include consideration of operative consumables, patient care, and capital costs.	

Table 2. Response to Public Comments on Draft Report

Reviewer	Comment	Disposition
Scott Adams (Pullman Regional Hospital)		
	"We have been providing robotic assisted laparoscopic surgery since December of 2011. We have performed about 35 cases to date. We have one trained urologist, 2 trained gynecologists, and one trained general surgeon. Since we began providing robotic assisted surgery we have seen an overall decline in the length of stay for all robotic assisted surgery patients to about 2 days. Hysterectomy patients have an average length of stay of 1 day. Blood loss for all procedures has declined and for hysterectomies the average blood loss is less than 50 cc. Patients comment on better pain control, quicker recovery time, and returning to their normal daily activities sooner. We have found this to be a truly break-through improvement in surgical outcomes for the specified procedures and feel that it warrants continued recognition for payment by the Health Care Authority. A dramatic improvement that is often overlooked is the tremendous influence that this new technology has on the surgeon. I have heard trained robotic surgeons tell me that this technology has changed their practice and they know they are able to treat patients in a minimally invasive manner that previous to this technology would have had to have open surgery. Additionally, the positive impact on the surgeon cannot be overlooked. Less fatigue, higher degree of visibility, improved ergonomics all argue for a better outcome for the patient. We urge your continued support for the availability of surgical technologies that provide better outcomes and lower costs for patients."	*Thank you for your comment.* *No changes to draft report.*
Kristen Austin, MD (Swedish Medical Center)		
	"I use robotic surgery for hysterectomies, myomectomies, and pelvic floor suspension. The daVinci technique allows for patients to return to work more quickly than standard laparoscopy or open cases due to decreased pain. They also use less post operative pain medication, have fewer infections, less blood loss, and fewer postoperative complications. As a surgeon, my back pain is drastically improved after switching to the daVinci robotic technique. I have done standard laparoscopy for many years and was beginning to have back pain that was	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	threatening my ability to continue practicing medicine. This benefits patients, because they will have more experienced surgeons able to operate longer. Thank you for your concern."	
Ralph Aye, MD, FACS (Swedish Cancer Institute)		
	"I'm a surgeon and former chief of surgery at Swedish Medical Center. Our group made a conscious decision to enter robotic surgery and now use it for selected thoracic and esophageal procedures. I have a few thoughts. 1. The robot allows surgeons with average or limited minimally invasive laparoscopic skills to do more complex cases that they would otherwise perform open. It most cases that would result in a longer hospital stay and a longer recovery. Most of the studies showing lack of benefit to the robot compare results with surgeons highly skilled in both laparoscopic and robotic surgery and would therefore not show this dynamic. 2. The robot is being over-utilized by surgeons wanting to improve their skills or to market their practice. This is natural with any newer technology. 3. Robotics will continue to improve and increasingly provide benefit. It is important to support its advance. 4. If restrictions are necessary for financial reasons, it would be much preferable to create boundaries either by institution or practice rather than prohibiting it altogether."	*Thank you for your comment.* *No changes to draft report.*
Michael Blee (Kootenai Health)		
	"As a Healthcare administrator and a recent robotic heart surgery patient (Mitral valve repair) I think that it is important that I share with you how very different can be the course a "Robotic assisted surgery" patient from that of a patient undergoing a traditional open procedure:	*Thank you for your comment.* *No changes to draft report.*

<table>
<tr><th>Reviewer</th><th>Comment</th><th>Disposition</th></tr>
<tr><td></td><td>
<table>
<tr><th>Parameter</th><th>Averages (per Society of Thoracic Surgery) for open procedures</th><th>My experience with a Robotically Assisted Procedure</th><th></th></tr>
<tr><td>Hours spent in intensive Care post procedure</td><td>68.7</td><td>Less than 12</td><td></td></tr>
<tr><td>Post procedure Ventilator hours</td><td>22</td><td>Less than 4</td><td></td></tr>
<tr><td>Total days in spent in the hospital post procedure</td><td>9.1</td><td>Less Than 3</td><td></td></tr>
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In addition to the above, I think that it is important to note that I was able to return to normal activities on my 5th post operative day & in fact was mowing my lawn on my 7th post operative day.
Lost time from work was far less in my robotic experience (7 days total) than the typical 6-10 weeks that we see in traditional open procedures.
In short, if my experience is any indicator of the reduced hospital resources consumed and the vastly shortened recovery times that can be realized through the use of Robotic assisted surgery, then this is a technology that should encouraged for all appropriate procedures.”
</td><td></td></tr>
<tr><td colspan="3">Steven R. Brisbois (Sacred Heart Medical Center)</td></tr>
<tr><td></td><td>“I have dedicated my career to MIS. I began doing complex Laporoscopic surgery in the 80's, and performed the first laporoscopic hyst in the state of Wash in 1990. When I was appproached in 2005 re doing robotic surgery, I asked the question "will the robot allow me to perform procedures using MIS that I am currently unable to do, or allow me to do them safer and better?" At that time, no one could answer that question. I began performing robotic Gyn in 2006. After a few cases, the answer to my question became obvious----it was a resonding yes! I weekly perform cases that I never could perform with straight laparoscopy. These include: 1 Large patients. I not only operate on pts with BMI's in the 50's, but also, 60's, 70's, and recently 80's. The alternative for these patients would be</td><td>Thank you for your comment.
No changes to draft report.</td></tr>
</table>

Reviewer	Comment	Disposition
	an open laporotomy with very high morbidity, and prolonged stays. My robot pts go home the same day, or the next AM. 2. Sacrocolpopexy. Previously, these pts required a complex laporotomy with high morbidity. Using the robot, these pts now either go home the same day, or the following AM. 3. Myomectomies. I have done fibroids to 27 weeks size with the robot, and taken out as many as 36 fibroids at one time. Again, they either go home the same day, or the next AM. What I am able to do with the Robot was unheard of in the past. Patients come here from west Washington, Oregon, Idaho, Mt, and as far away as North Dakota to seek MIS, as most of them have been told that they will require an open procedure. I could not practice what I do without the robot. I do not believe that it should replace all other MIS procedures. I still do TVH's, and straight laparoscopic hysts in appropriate pts. However, for the above pts, the robot has revolutionized safer care."	
D. Mark Brown, MD (Southwestern Washington Urology Clinic)		
	Radical Retropubic prostatectomy is the GOLD standard in therapy for localized prostate cancer. All other therapies are compared to this GOLD standard in terms of efficacy, safety, morbidity, cost, and mortality rates. I have been performing this operation for 22 years and am an expert at Open Radical Retropubic Prostatectomy with Bilateral pelvic Lymph Node Dissection. Comparing Open Radical as above to Robotic Assisted Radical Prostatectomy reveals the following: IN EXPERIENCED HANDS: Open Procedure / Robotic Procedure Operating room time: 70 to 120 minutes / 180 to 360 minutes 1.17 to 2.0 hours / 3.0 to 6.0 hours Blood Loss: 20 to 300cc's / 150 to 500cc's Operative Mortality: 0.2% / 0.6% Impotence Rates: 25 to 75% / 10 to 60%	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	Incontinence Rates: 0.2% to 5% 20% to 45% Cost: $8,130 $15,550 Average Length of Stay: 23 to 96 hours 23 to 48 hours Wound Infection Rate: 0.1 to 1.5% 0.1 to 0.8% Postoperative Pain: 48mg morphine 10mg morphine As you can clearly see the only benefits to the robotic procedure are decreased pain, marginally decreased length of stay and perhaps slightly less wound infection rates. The open procedure is better in terms of cost, operative time, blood loss, and incontinence rates. The most important thing is the open procedure has a lower operative mortality rate because surgeons are doing these procedures untrained, thinking that the robot gives them an advantage when it really doesn't and they are doing an extremely dangerous operation with relatively little training. Hope this helps. I would love to testify in a public hearing about this issue!!"	
Michael Burke, MD, FACS (Valley Medical Center)		
	"With the advent of Robotic technology we are entering a new phase in virtual surgery with more precision and less trauma to patients. The dichotomy between new technology and evidence based medicine is that the early lack of data to demonstrate value inhibits the training, use and deployment of technologies that will likely benefit a significant number of patients. Robotic surgery allows surgeons to perform minimally invasive surgery with better visualization and precision than in laparoscopic procedures. Unfortunately the cost and training in robotic surgery is expensive but the benefits to the patients will be realized as it has been in laparoscopic surgery. The cost will come down with more competition as it has in laparoscopic surgery. The learning curve for specific robotic procedures varies. Prior experience in laparoscopic surgery is extremely valuable in reducing the robotic learning curve. Colon, pancreas and GI surgery can be done with less morbidity and hopefully better outcomes. Robotic programs should critically analyze their data to bolster the evidence to support this valuable technology."	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
Eve Cunningham		
	"For the past year and a half and I have embraced the newest technological advancements in gynecologic surgery with fervor. My leap to training and using the robot for gyn surgery has helped so many of my patients. Prior to using the robot for gyn surgery, I was attempting a laparoscopic approach in complex surgical situations. While laparoscopy is still a valuable tool, I found that my dependence on my assistant surgeon during the case and my limited ability to articulate the laparoscopic instruments would sometimes lead to requiring an open laparotomy incision (large incision) in order to finish the case. This was most unfortunate for my patients, especially the morbidly obese patients with complex medical problems. Ever since I started using the robot, I have only used a laparotomy incision (large incision) on one patient in gyn surgery. The robot has given me the tools I need to perform minimally invasive surgery on some of the most complicated and challenging patients. Patients with Medicaid are often some of the most challenging to operate on. By using the robot, I have been able to minimize their stays in the hospital and shorten recovery times. My understanding is that Medicaid does not pay any extra fees for robotic surgery on patients. The robot is considered a laparoscopic tool and therefore all cases are reimbursed as though they were straight laparoscopic. If this is the case, then I confused as to why the state would be concerned as to whether Robotic surgery is covered in their plans or not. Technological advancements in medicine are not going away. Twenty-five years ago, the utility of laparoscopy was questioned. Now, laparoscopy is considered standard of care. Robotic surgery is not going away any time soon. And, patients benefit from robotics by avoiding large incisions that often lead to secondary complications such as infections, seromas, separations and longer healing times."	*Thank you for your comment.* *No changes to draft report.*
Paul H. Eun, MD (Dedicated Women's Health Specialists, Inc)		
	"Although not necessary for everyone, robotic surgery has clear benefits for some patients. It allows patients the opportunity to undergo minimally invasive surgery when there are no other reasonable alternatives except traditional open surgery at significantly greater cost due to longer hospital stay and recovery time."	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
Michael Florence, MD, FACS (Swedish Medical Center)		
	"Opinion: Although Robotic assisted surgery has clear advantages over traditional laparoscopic surgery for certain specific procedures, it adds to the cost of the procedure and thereby reduces hospital profits on a case by case basis unless the use of the Robot significantly decreases LOS and complication rates. For prostatectomy, this may well be the case, but for some other procedures it is less clear. Robotic assisted surgery is clearly part of the "medical arms race" in that purchasing the equipment is driven by the desire on the part of hospital administrators to maintain their market share in a given community. Some surgeons have commented that the best business decision is to buy and market a robot, but to never use it. Procedures that would be controversial include cholecystectomy and oophorectomy. Clearly the push by the device manufacture to use a single port robotic approach to cholecystectomy is purely driven by profit. The likelihood that we could ever prove a single port robotic approach is safer and more cost effective than current laparoscopic approaches is extremely hard to imagine. Multiple other procedures fall in the middle including robotic gastrectomy, pancreatectomy, and colectomy to name a few. The safety, efficacy and cost benefits might favor the robotic approach, but would require considerable study."	*Thank you for your comment.* *No changes to draft report.*
Joel B. Flugstad, MHPA (Swedish Medical Center)		
	"This letter contains comments and recommendations on behalf of The Robotics Committee at Swedish Health Services (SHS) in response to the Health Technology Assessment draft evidence report (HTA) for Robotic Assisted Surgery (RAS). We commend the efforts that have been undertaken by this HTA. In support of continually working to improve patient care, our comments are as follows: **JUSTIFICATION OF INTERESTS** SHS currently has the largest robotics program by volume and specialty within Washington State. Established in 2005, the program has grown each consecutive year, and performed over 1,3000 RAS cases in 2011. The program currently operates at 4 SHS campuses, First Hill, Cherry Hill, Edmonds, and Issaquah, with physicians practicing in the following disciplines:	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	• Urology • Colorectal • General • Gynecology • Gynecologic Oncology • Otolaryngology • Thoracic • Cardiac Surgery SHS has developed and implemented an extensive administrative framework to support a sustainable robotics program that strives to deliver high quality, appropriate care, in an efficient environment. As the program has evolved, SHS and affiliated providers have raised many of the same concerns contained within this HTA. SHS has effectively mediated many of these concerns through collaborative efforts between surgeons, staff, management, and vendors. These efforts include standardized credentially of physicians and allied health providers seeking privileges for robotic surgery, ongoing quality assessment of robotic surgical procedures, and data collection of robotic surgeries for research and publication.	
	COMMENT 1 In response to the HTA's recognition regarding the low volume of literature related to RAS, RAS is a relatively new surgical procedure. Published literature often is many years behind new technology. A key example of this was with the adoption of laparoscopic surgical techniques. While the use of laparoscopy and other minimally invasive methods are now commonly accepted as the standard of care, at their inception, literature supporting their use was lacking. RAS, especially as a subset of minimally invasive technique, has unfolded in the same manner. The current literature cited by the HTA compares an immature experience with RAS with a mature experience in open and laparoscopic techniques. This makes meaningful comparison between techniques challenging especially at this early stage in adoption. **RECOMMENDATION 1** In light of the HTA's recognition of the limited volume of literature related to RAS, further study and data related to RAS must be generated before meaningful comparisons can be made to current treatment standards. Furthermore, at this time there is no data to suggest that RAS is unsafe or compromises patient care. SHS requests that the analysis continue until sufficient literature exists. At such time, the HTA can effectively generate recommendations related to the efficacy of the modality	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	as a whole.	
	COMMENT 2 Improved outcomes associated with RAS has been recognized in centers where a high volume of surgery is routinely performed. Several studies have shown that the greater the experience of the surgeon performing robotic procedures, the better the overall outcomes. Experience of not only the surgeon is important, but also of the nursing staff, anesthesia staff, and ancillary care team. This would suggest that centers that perform a high volume of RAS would be the most efficient and provide the best quality of care. This model has proven successful in other care disciplines such as stroke and trauma where regional centers of excellence are created to facilitate best practices and provide the highest level of care. SHS has grown to become the regional leader in RAS and has more experience providing RAS procedures than any other center. The organizational structure of our RAS program has allowed ongoing assessment of RAS quality measures such as length of stay, blood loss, operative time, and complication rate. These outcomes are reviewed by our Robotics Steering Committee and recommendations are made to improve outcomes for each specialty performing RAS. Each specialty performing RAS has maintained on ongoing collection of data for review and publication. This allows improvement in RAS by assessing outcomes. Finally, SHS has also taken an active role in training other surgeons from across the country in RAS. **RECOMMENDATION 2** Regional data regarding RAS and its comparative efficacy to open surgery can be obtained from regional centers of excellence. This data it would be more meaningful in making recommendations for RAS in the state of Washington. Our recommendation is that HTA work with high volume RAS centers to obtain quality data for assessment and determination of future scope of robotic surgery practice in our state.	*Thank you for your comment.* *No changes to draft report.*
	COMMENT 3 Currently there are additional costs associated with performing RAS procedures. However, the cost to the state of Washington for RAS is the same charges as the laparoscopic procedure given the equivalent CPT codes for robotic and laparoscopic surgery. There is no additional charge to insurance company's or the state for robotic-assisted procedures. The increased capital costs associated with	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	robotic surgical systems have been incurred by hospital systems in an effort to provide patients with state of the art surgical care. In addition, studies that look at operating room costs do not take into account the cost savings created by shorter length of hospital stay which has been clearly demonstrated in multiple studies of RAS. The economic advantage to employers when a patient is able to return to work sooner after RAS as compared to open surgery is difficult to measure, but represents a downstream advantage of RAS over conventional surgery. **RECOMMENDATION 3** Cost analysis of RAS versus open or laparoscopic surgery should include the savings associated with shorter length of stay and earlier return to work.	
	COMMENT 4 Operative times associated with RAS are by in large longer than the open surgical counterpart in the initial experience of robotic surgeons. This is related to increased time associated with gaining minimally invasive access to the body. However, with experience the RAS procedure approaches the operative times associated with the open surgical procedure. In our experience with RAS at SHS, the operative times associated with high volume procedures such as prostatectomy and hysterectomy are now equivalent to the open surgical times and in some cases faster. There is one RAS procedure that has demonstrated faster operative times than the open counterpart from the beginning and this is trans-oral surgery for base of the tongue cancer. This use of RAS is not only more efficient than the open procedure but is less morbid for the patient and leads to better functional outcomes. **RECOMMENDATION 4** With increasing experience, the costs associated with longer operative times in RAS procedures will decrease. Therefore, further study should be undertaken in high volume RAS centers to determine the true cost of the procedure as it related to operative time.	*Thank you for your comment.* *No changes to draft report.*
Brian Fong, MD, FRCS(C) (Western Washington Medical Group)		
	"Within urologic surgery, robotic surgery has transformed the quality and effectiveness of care I provide to patient with urologic disease such as prostate cancer, kidney cancer, and congenital urinary obstructive diseases. While the upfront costs may be higher, the actual overall costs are less,	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	as patients consistently have a decrease hospital stay, decreased rate of blood transfusion and decreased complication rate. An unmeasured advantage is the quicker return to work for patients which increases their productivity within their employment environment. I raise my concerns about the potential for a decision of refusal of reimbursement for minimally invasive robotic-assisted surgery when my own experience suggests excellent outcomes, overall cost effectiveness, and improve patient satisfaction. With robotics, surgery can be offered to a wider range of patients (obesity, prior abdominal surgery) with excellent outcomes. In kidney cancer, there is the benefit of preservation of kidney function with robotic partial nephrectomy and decreased long term possibility of renal failure and the potential health care cost related to this (esp. dialysis). My belief is that within urologic surgery there is no going back to open surgery or traditional laparoscopy as the robotic approach is superior to those old techniques. It would be a great tragedy for Washington State Health Care Authority to declare urologic robotic surgery to be a non-covered procedure given the multiple medical studies suggesting equivalence and possible superiority to traditional open/laparoscopic techniques with the bonus of less morbidity and consistent excellent outcomes. Washington state has an impressive track record of building high technologies industries (e.g. computers, aviation) and high-tech surgery should be supported with the same pride and ambition."	
Theresa Froelich, DO (University Place Medical Clinic)		
	"To Washington State Health Care Authority, I have been doing robotic laparoscopic surgery for the last 2 years and it certainly has a place in women's health care. This procedure improves outcomes in obese women, women with prior abdominal surgery and it shortens recover (decreases length of stay). Women are back to work sooner with less post operative complications. I believe it would be a disservice to your patients to not offer this innovative procedure."	*Thank you for your comment.* *No changes to draft report.*
Heidi J. Gray, MD (University of Washington)		

Reviewer	Comment	Disposition
	"I am a Gynecologic Oncologist in Washington State who has specialty training in robotic surgery for gynecologic cancer. I am writing you to strongly consider the benefits of robotic surgery for women patients with gynecologic malignancies. I used to perform over 80% of my endometrial cancer hysterectomies as an open procedure with 3-7 day hospital stay and 20-50% wound infection rate. Most patients with endometrial cancer are overweight, obese or morbidly obese (BMI >30). The improved technological advances of robotic surgery has enabled me to now perform 70-80% of my patients with endometrial cancer with minimally invasive surgery as robotic assisted laparoscopy. They stay overnight in the hospital, have less infections, quicker recovery, less blood loss, less pain. I have less postoperative office visits for wound care and complications compared to open surgery. There are many studies now showing the benefit of robotic assisted surgery over open procedures. Please contact me if you have any further questions. I have no financial ties or disclosures to Intuitive."	*Thank you for your comment.* *No changes to draft report.*
Peter Grimm, DO (Prostate Cancer Center of Seattle)		
	"The effectiveness of Robotic surgery for Prostate cancer compared to open prostatectomy or other treatments should deal specifically with effectiveness of the treatment to eradicate cancer as a sole modality. In prostate cancer the most specific measurement is PSA based evaluation, as the result is entirely dependent on the effectiveness of the treatment. Other measures such as overall survival, metastasis free survival and other endpoints not PSA based are dependent on the nature of the disease and the overall health of the patient (as well as the effectiveness of the treatment) and therefore are less reliable tools for comparing results of the treatment itself."	*Thank you for your comment.* *No changes to draft report.*
Patti Holten		
	"As a patient of a Robotic assisted heart valve surgery, I wanted to give my input on the difference between a Robotic surgery and an open sternotomy. There is more than a couple positives to be said about the Robot, recovery time is much faster than an actual open sternotomy, with only a 3 day stay in the hospital and discharged home without restrictions so your back to work and your daily living that much faster, compared to the 5 to 7 day stay in the hospital with an open sternotomy along with weeks of care giving at home.	*Thank you for your comment.* *No changes to draft report.*

Reviewer	Comment	Disposition
	I have the pleasure of working in a cardiothoracic surgeon's office and I see the amazing difference between a patient having a Robotic surgery done and the one who has an Open Sternotomy. We see the occasional patients with infection and those with lingering depression. From my own personal experience of having a Robotic assisted heart surgery, my recovery was so much faster and all in all was so much better, I feel great and didn't have all the down time that comes with open heart surgeries."	
Catherine Hunter, DO		
	"As a practicing OBGYN for nearly twenty-seven years, I have seen many changes and innovations in my field; first, laparoscopy, fiber optics, anesthetic improvements, better electrocautery instruments, etc. There is no innovation in surgery that has impacted my ability to care for my patients as much as the robot. The haptics of robotic surgery allow the surgeon to move on all planes of articulation, not just pronation, supination, pushing and pulling. Acute angles around difficult or large pathology become manageable. Three-D vision allows for unparalleled visibility. I can get my scope within inches of structures to assess an adhesed area or difficult anatomy. Now 500-lb endometrial cancer patients can have minimally invasive surgery and be home the next day, resuming nearly all activities and start adjunctive therapy sooner. In short, almost all patients now have access to minimally invasive surgery. But, just as the experienced pilot must spend many hours in the cockpit on normal, routine flights to be able to make the decision and land the plane in trouble safely in the river, so must the robotic surgeon spend time in the 'cockpit' honing his/her skills for the challenging cases. To limit or restrict this is a disservice to all patients, I might even say discriminatory to 'normal' patients, and to the surgeons who spend the time and energy to maintain excellence in their field. Of course, you can find any number of studies showing better overall outcomes, length of stays (my patients go home the same day), complications, blood loss, and patient satisfaction. Of my last 210 robotic cases I have opened three. Please allow the surgeons to make the medical decisions we were trained to make in the best interest of our patients. For your information, Please reference the two editorial letters regarding this subject in the March, 2012 issue of OB.GYN News on page 16. Thank you very much for your consideration in this matter. "	*Thank you for your comment.* *No changes to draft report.*
Peggy Hutchison, MD (Seattle OB/GYN Group)		

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	"I am a Gynecological surgeon. I work at Swedish Medical Center. I do all types of hysterectomies including vaginal hysterectomies, abdominal hysterectomies, and Robotic laparoscopic hysterectomies. I have done over 100 Robotic laparoscopic hysterectomies. Prior to this I had done about 250 Laparoscopic hysterectomies. I have a very clear perspective on the difference between the 2 approaches. The Robotic assisted laparoscopic total hysterectomies is a great improvement over the laparoscopic hysterectomy. The visualization is in 3-D and allows the surgeon to see the uterine vessels, the bladder and the ureters better. The visualization is such an improvement that I have been able to remove larger uterus, dissect the bladder off the uterus with more precision and see the ureters to avoid injury. I can also see the uterine vessels and transect them saver and far away from the bladder and ureters. This provides added safety to the patient. I have also been able to do hysterectomies on women who have endometriosis and adhesions or scar tissue from prior surgery. These cases would never have been done with laparoscopy only. Again, the visualization as well as the fine instrumentation has greatly enhanced the ability to do this. This allows a woman to avoid a large open incision with greater risk of infection, bladder, bowel and ureteral injuries, bowel obstructions, and deep venous thrombosis. The patient with a Robotic hysterectomy will not only have fewer complication, their recovery is better. They can be back to work in 2 weeks, they use far less narcotics, they are less constipated and they are very happy with the outcome. In addition, my patients leave the hospital in less than 24 hours. They are up walking, eating and functioning at a very high level. Some of them use no narcotics. The articulation of instrumentation is superior with the Robot as compared with traditional laparoscopy. They allow you the ability to rotate the instruments in such a way that there is less risk of injury to other organs. You are also able to grasp the major vessel of the uterus with more accuracy. You are able to move into anatomical spaces you could not do with traditional laparoscopy.	*Thank you for your comment.* *No changes to draft report.*

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	When you operate on a person you can encounter unexpected problems which complicate you surgery. Your patient can have adhesions, scarring from endometriosis, obstructed view of the uterine vessels, a bladder that is adherent to the surface of the cervix or uterus, or vessels that are difficult to get to with traditional no articulated instruments. There is no doubt the robot is far superior in these situations than traditional strait stick laparoscopy. All of these increase the chance the patient will need an open laparotomy for their hysterectomy if it is approached by traditional laparoscopy. After many years of operating I have told many people the da Vinci Robot is the greatest invention in medicine in 25 years. Every MD that starts to use the Robot in gynecology will never return to straight stick laparoscopy or large open incisions. The da Vinci Robot is better for the patient and the MD. It is safer and much easier to use than traditional laparoscopy. It allows for complicated surgeries to be performed through small incisions with fewer complications, less pain, better visualization, and faster recovery to the work force. In addition, when doing a total hysterectomy the vagina has to be closed with sutures. It is very difficult to suture with tradition laparoscopy. When using the da Vinci Robot the ability to suture is simple and very easy. Your ability to tie knots is better. Your ability to hold the tissue is better and more delicate and the risk of injuring the bladder or ureters is decreased. Supporting modern technology which is changing the face of women's health care is very important. This is a medical technology that is well studied, used throughout the United States and a major improvement over all types of approaches to hysterectomies. Please don't revert back to old technology. Please allow medicine to continue to progress and deliver the best health care to women. If you would like to hear from me in person I would be happy to testify on behalf of my patients. I would be happy to have my patients also come to tell you how well they did with this surgery and how happy they are with the outcome. The return to society is good, but it will be greater and greater as every hysterectomy is done either with the da Vinci Robot or by a vaginal approach. There will be less time off work, fewer	

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	readmissions to the hospital, lowered hospitals stays, less narcotic use, and healthy women. "	
Intuitive Surgical		
	"Robotic surgery's primary contribution has centered around its ability to enable complex surgeries to be performed in a minimally invasive fashion. Prior to the introduction of robotic surgery, the percentage of prostate, cervical, endometrial, and other types of cancers and complex pathologies treated with minimally invasive surgery (MIS) was a small minority. Save for a handful of highly trained surgeons, the precision, articulation, and vision necessary to safely and efficaciously complete these procedures did not allow meaningful adoption of MIS. However, with the introduction of robotic surgery, the majority of these procedures are not done minimally invasively. This has had a profound effect on the economics and outcomes of these procedures: Patients go on to adjuvant therapies sooner and healthier; they leave the hospital sooner, thus consuming fewer resources and costing less; while returning to their normal lives more quickly. This enabling of MIS for complex and oncologic surgeries has provided substantial value to everyone in the treatment equation, from patients to surgeons to hospitals to payers. In general, Intuitive Surgical finds this draft report to be a thorough review covering many of the prospective and retrospective comparison studies of outcomes following prostatectomy, hysterectomy, nephrectomy, colorectal, general, thoracic and cardiac surgery performed with robotic assistance, laparoscopy, or an open approach. We note, however, that there are gaps in the representation of available comparative studies of robotic-assisted surgery and insufficient detail on the methods of statistical analysis. We appreciate the significant amount of work and effort that was required to complete this draft report and the pressing need for these types of analyses. The peer-reviewed clinical literature base pertaining to the da Vinci Surgical System and its uses is growing at a rate of approximately 4-5 articles per day. At present there are over 4,800 peer-reviewed articles related to the *da Vinci* Surgical System of which more than 570 are comparative cohort studies. Intuitive Surgical believes it is important to insure the inclusion of all relevant previous health technology assessments and published peer reviewed articles in order to complete a comprehensive analysis of the clinical benefits of the da Vinci technology. As a document that will be used by policy makers, it is important	*Thank you for your comment.* *No changes to draft report.*

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	to provide the complete landscape for accurate and concise decision making."	
	The main parts of the Washington State HTA (WASHTA) appear to be based on the findings of the CADTH (Canadian Agency for Drugs and Technologies in Health) Technology Report, Issue 137, September 2011. We are aware of a more recent HTA report conducted by the Health Information and Quality Authority, Ireland (HIQA) published on Jan 11, 2012. We believe that this report would supersede the CADTH findings. The HIQA HTA dealt with the same research questions as the CADTH and included data through Jan 2011. Thus the HIQA report is more recent, of equal quality and at least as comprehensive as the CADTH report (HIQA included Urology, Gynecology, Cariothoracic and ENT/Head & Neck indication). We are enclosing a copy of the HIQA HTA for your review. On page 27 of the hIQA report it is explicitly stated that "the systematic review performed by the Canadian Agency (CADTH) was updated with appropriate analysis of the data and expert support by the CADTH team." We believe it is advisable for the Washington State Health Care Authority to include the highly relevant, recent HIQA HTA (which followed the CADTH methodology) and exclude the more outdated CADTH HTA in accordance with the methodology description which appears on page 4 of the WASHTA draft report.	*Thank you for your comments.* *A 'best evidence' systematic review methodology was used to complete the report. We strictly adhere to "the methodology description which appears on page 4 <Executive summary> <in detail in Methods section page 26-30> of the WASHTA draft report"…as excerpted below:* *The Canadian Agency for Drugs and Technologies in Health (CADTH) technology assessment (TA) titled Robotic-assisted Surgery Compared with Open Surgery and Laparoscopic Surgery: Clinical Effectiveness and Economic Analyses (2011) was used, in consultation with the Washington HTA, as the primary evidence base for key questions #1 through #4. Where there were high quality comprehensive reviews, they were summarized. A MEDLINE® literature search (September 2011 through January 2012) was completed to identify subsequently published studies. If*

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		there were no high quality reviews identified for a procedure, a search, appraisal, and summary of primary individual studies were completed for the past 10 years (January 2002-January 2012). *The CADTH TA was updated to publication in September 2011. The cited Health Technology Assessment of Robotic-assisted Surgery in Selected Surgical Procedures, published by the Health Information and Quality Authority (HIQA), Ireland September 21, 2011 as noted on page 28 of this document, "A systematic literature search using the CADTH HTA approach was carried out to update the review to January 2011." This TA, therefore, was superseded by the CADTH TA and was excluded. Furthermore, the meta-analyses performed in the HIQA TA, as compared to the CADATH TA, included the identical studies, though fewer, with smaller pooled sample sizes. This further supports the more current status of the CADATH TA and underscores the*

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		CEbP's use of a "best evidence" systematic review methodology.
	"The replacement of the CADTH HTA by the HIQA HTA would have the following key implications: **Prostatectomies** • Addition of data to support higher percentage of patients who regain urinary continence. (Robotic versus Open surgery). • Statistically significant reduction in complication rates in robotic surgery versus open surgery • Demonstration of a larger reduction in length of stay after robotic surgery versus open surgery than was demonstrated in clinical articles included in the CADTH review. • Cost-effectiveness analysis rather than cost minimization analysis o A cost-minimization analysis as performed by CADTH assumes no differences in outcomes between treatment groups. However, HIQA acknowledged the superiority of RALP (Robotic Assisted Laparoscopic Prostatectomy) versus open and thus performed a cost-effectiveness analysis. The CADTH approach raises concerns as today's evidence does suggest superiority and not equivalent outcomes. o The economic analysis performed by the CADTH does not seem appropriate due to the dramatic differences in the healthcare economic factors between the Canadian and U.S. health care systems.	*Please see comment above addressing the HIQA HTA.*
	Hysterectomies • *Robotic assisted versus open radical hysterectomy*: Statistically significant reduction in extent of blood loss, transfusions and complication rates in favor of robotic surgery versus open hysterectomy. • *Robotic assisted versus laparoscopic radical hysterectomy*: Statistically significant reduction in extent of blood loss, transfusions and complication rates in favor of robotic assisted versus laparoscopic radical hysterectomy. Operating time demonstrate no statistically significant difference between robotic and laparoscopic approaches. • *Robotic assisted versus laparoscopic hysterectomy for benign disease*: Statistically significant reduction in complication rates, conversion to open surgery and transfusion rates. Operating time demonstrate no statistically significant difference between robotic and laparoscopic approaches.	*Please see comment above addressing the HIQA HTA.*
	Additional Literature Search Although the Washington State HTA performed an extensive literature search spanning the past ten years including all English language articles, there are potentially relevant articles that this search failed to identify. For example, the Journal of Robotic Surgery, a PubMed reference journal that is available online at: http://www.springerling.com/content/120470/ is not represented. In all, we	*Thank you for your comment.* *We strictly adhere to the methodology description which appears on page 4 <Executive*

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	found twenty four relevant comparative articles on robotic surgery in JRS covering robotic prostatectomy (10), partial nephrectomy (1), hysterectomy for cancer (9) and benign hysterectomy (4) that were not included in the present report. There were other publications with potentially relevant data that are also missing from the data analysis. Across all of the covered surgical specialties, we found 38 comparative articles that we believe are *highly informative* to the scientific discussion of robotic surgery. Of these, 30 were published prior to January 31st, 2012, the reported inclusion date for the WASHTA. The remaining 7 have been published since the end of the search period, but contain highly relevant, large sample size, comparative studies that we believe should be considered in the final report. For your convenience, we have also included in Appendix B (Urology Articles) and Appendix C (Gynecology Articles) 167 additional comparative articles which seem to be relevant to the discussion, but were not cited in your report.	*summary> <in detail in Methods section page 26-30> of the WASHTA draft report. The search strategy used MEDLINE® to identify relevant articles. Journals that are not indexed in MEDLINE® were therefore not included in this report.* *The submitted articles have been reviewed and citations that met the report's inclusion criteria (n=20 studies) have been incorporated into the report. Excluded studies, along with rationale for exclusion, are listed in the Notes section.*
	Data Extraction, Analysis, and Reporting Although this report includes 51 prostatectomy robotic comparison papers, we feel that the weight of evidence found in the missing papers could affect the conclusions reported in the WASHTA report. The combined study size of the missing papers is significant. For example, by including just three articles on Prostate Cancer (Trinh (Appendix A #2); Tewari (Appendix A #3)), the analysis would benefit from data on an additional 167,184 ORP (Open Radical Prostatectomy) patients, 57,303 Laparoscopic Radical Prostatectomy patients and 62,389 RARP (Robotic Assisted Radical Prostatectomy) patients. It is unclear how the results of multiple meta-analyses as well as individual studies were combined from a statistical standpoint as well as how the issues of study heterogeneity and publication bias were quantified.	*Thank you for your comment.* *The additional studies (Trinh 2012, Tewari 2012) were both published after this report's end search date (January 2012), and are therefore not included in this report.*
	Additional Considerations After review of the WASTHA report, we would also like to point out the following: On page 7 of the WASHTA report it states that "There is low strength of evidence that robotic surgery was a safe and effective technique for performing hysterectomy on morbidly obese women."	*Thank you for your comment.* *Gehrig's inclusion in the CADTH TA precluded its inclusion as an*

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	The WASHTA, however, overlooked multiple publications within the specified timeframe which draw a different conclusion: • Seamon, L.G., S.A. Bryant, et al. (2009). "Comprehensive Surgical staging for Endometrial Cancer in Obese Patients: Comparing Robotics and Laparotomy." Obstet Gynecol 114(1): 16-21. o This case-matched comparison of robotic hysterectomy to abdominal hysterectomy in an obese patient population demonstrated a lower estimated blood loss (109mL vs. 394mL; p<0.001), a shorter length of stay (1 day vs. 3 day; p<0.001), fewer wound problems (2% vs. 17%; p=0.002), and fewer complications (11% vs. 27%; p=0.003) in the robotic cohort. • Gehrig, P.A., L.A., Cantrell, et al. (2008). "What is the optimal minimally invasive surgical procedure for endometrial cancer staging in the obese and morbidly obese women?" Gynecologic Oncology. 111(2008) 41-45 o This comparative study of robotic hysterectomy to laparoscopic hysterectomy in an obese and morbidly obese patient population demonstrated that the robotic group experience a lower blood loss (50ml vs. 150ml; p<0.001), a shorter operative time (189mins vs. 215mins; p=0.004), increased lymph node retrieval (31.4 vs. 24 nodes; p=0.004) and a shorter hospital stay (1.02 days vs. 1.27 days; p=0.0119).	*additional study. The Seamon article met inclusion criteria and has been incorporated into the report.*
	On page 18 of the WASHTA report, the Overall Summary section, provides a broad statement that, "the complication rates of robotic procedures are comparable to those of open and laparoscopic procedures." • This statement is contradicted on page 35 of the WASHTA report, which describes lower complication rates for robotic prostatectomy versus open surgery • Additionally, the paper by Carlsson et al (Carlsson 2010) reporting on 1,253 RARP versus 485 ORP, provides further evidence to show a conclusive advantage of robotics over open surgery and laparoscopic surgery. • Trihn 2012 and Tewari 2012 provide substantial evidence to show a conclusive advantage of robotics over open surgery and laparoscopic surgery.	*Thank you for your comment.* *The broad comment on page 18 in the Executive Summary addresses the general complication rates for all procedures. Complication rates for specific procedures (e.g., prostatectomy) are discussed individually under KQ2 for each procedure.* *Results of the Carlsson study, along with other studies, are included in the CADTH report and CADTH's meta-analyses.* *Trinh (2012) and Tewari (2012)*

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		were excluded from this report because both were published after the end search date.
	On page 20 of the WASHTA report it states "Each year, approximately 158,000 prostatectomy procedures are performed in the US (NCI 2011)" • The volume from third party data vendors such as AHRQ and Solucient which are based on payor claims estimate between 85,000-100,000 surgical prostatectomy procedures annually. • NCI, National Cancer Bulletin August 9, 2011, Volume 8 / Number 16 estimate 88,000 prostatectomies were performed in 2008.	*Thank you for your comments.* *Data from the National Center for Health Statistics, based on the National Hospital Discharge Survey, 2009 indicate that 158,000 prostatectomy procedures were performed in 2009 in the United States. Please see: http://www.cdc.gov/nchs/data/nhds/4procedures/2009pro4_numberprocedureage.pdf* *No changes to the report.*
	On page 21 of the WASHTA report it states that "nephrectomy is the most common treatment modality for kidney cancer, with an estimated 150,000 radical nephrectomies and 39,000 partial nephrectomies performed across the US between 2003 and 2008 (Kim 2011) • Please consider that the American Urological Association, in 2009 issued a clinical guideline declaring"…Partial Nephrectomy is now considered the treatment of choice for most clinical T1 renal masses, even in those with a normal contralateral kidney." ○ The literature demonstrates improved peri-operative outcome for Robotic Partial Nephrectomy, including lower warm ischemia time, and less blood loss.	*Thank you for your comments.* *No change to the report. The quoted passage provides background on the frequency of nephrectomy procedures, and is not intended to review guidance on the type of procedure that professional organizations recommend.*
	On page 32 of the WASHTA report it states that inconsistent results were reported for incidence of complications. The report states that through meta-analysis, retrospective studies, and high or good quality studies it did not show a significant difference. • Carlsson and Trinh 2012 both showed significant reductions in complications for Robotic Assisted procedures versus open procedures.	*Thank you for your comments.* *Results of the Carlsson study, along with other studies, are included in the CADTH report and*

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		CADTH's meta-analyses. *Trinh (2012) was not included in this report because it was published after the end search date.*
	On page 39 of the WASHTA report it states the following: "The cost of the robot included in this economic analysis is for the new model (*da Vinci* Si; US$2.6 million). However, the model reported in most of the literature is the older model (*da Vinci*; US$1.2 million). If this analysis had been carried out using the costs of the earlier model, the increased incremental costs of both comparisons (RARP vs. ORP and RARP vs. LRP), would have been roughly half what is reported above." • The pricing quoted in the WASHTA draft report is incorrect, the list price of the da Vinci Si System is $1.75 million U.S. dollars.	*Thank you for your comments.* *The pricing information has been corrected.*
	On page 41 of the WASHTA report it indicates that inconclusive evidence was found when comparing robotic hysterectomy to laparoscopic hysterectomy with respect to complications and length of stay. • Scandola, M., L. Grespan, et al. (2011). "Robotic-assisted Laparoscopic Hysterectomy vs. Traditional Laparoscopic Hysterectomy: Five Meta-analysis."Journal of Minimally Invasive Gynecology 18(6): 705-715. o Meta-analysis of 1,280 robotic hysterectomy patients vs. 1,386 laparoscopic patients found no difference in operative time but a shorter length of stay (Odds ratio =-0.43; CI=-0.68, -0.17), fewer conversions to laparotomy (Odds ratio = 0.49; CI=0.31, 0.77), and fewer complications (Odds radio = 0.68; CI=0.49, 0.94), all in favor of robotic hysterectomy	*Thank you for your comments.* *Scandola (2011) was not indexed in MEDLINE® at the time of our search (MEDLINE® index date Feb 24, 2012). However, given its publication during the search window, the article was reviewed. It did not meet inclusion criteria because it was superseded by the more comprehensive CADTH report.*
	On page 47 of the WASHTA report it incorrectly states that "Another cost-consequence study reported total mean per-patient costs in the robotic, laparoscopic, and open surgery groups as $50,758, $41,436, and $48,720, respectively." • These dollar values are actually patient charges, not costs to conduct the procedures. Charges are typically not reflective of the true costs of a procedure.	*Thank you for your comment.* *The text has been revised for clarity.*
	On page 52 of the WASHTA report, the following statement is made: "Most of the sub-populations listed in the key questions of the WASHTA report were not reported in [CADTH] (2011). Information about surgeons' experience was insufficient to perform a sensitivity analysis regarding the impact of the learning curve on clinical outcomes for any of the nephrecotmy study results"	*Thank you for your comment.* *"Bjayani 2009" appears to refer to Wang & Bhayani (2009), which*

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	• Consider Bjayani 2009, Journal of urology: In this retrospective series, Robotic Partial Nephrectomy had some significant benefits compared with Laparoscopic Partial Nephrectomy, including shorter ischemic times and a shorter hospitalization. ○ Reported results were obtained by a surgeon with expert laparoscopic skills versus the same surgeon during their learning curve of Robotic renal procedures.	*was included in the CADTH report.*
John Paul Isbell, MD		
	"I am a practicing OB-GYN physician board certified since 1983. I have used robotic surgery for over 2 years at Evergreen Hospital Kirkland, WA. Though skeptical initially, I cannot imagine not having this surgical tool available after 2 plus years of use. The improved recovery patients experience is phenomenal. I am able to perform this minimally invasive surgical technique on obese patients, nulliparous patients, and patients with large uteri. Prior to this technology, a major abdominal incision would have been required in most cases. Besides the amazingly rapid recovery, patients experience marked reduction in pain, reduction in excessive operative blood loss, and reduction in time spent hospitalized (an overnight stay is all that is required in 99% plus). I would place robotic surgery's impact on gynecologic surgical patients in a comparable position as was the development of ultrasound technology to the management of obstetrical patients."	*Thank you for your comment.* *No changes to draft report.*
Frank Kim, MD		
	"I am an urologist who has been performing robotic surgery especially for prostatectomies and partial nephrectomies. Clearly robotic approach is the standard of care for these surgeries as oppose to open or pure laparoscopic approaches, in reducing morbidities."	*Thank you for your comment.* *No changes to draft report.*
Richard Koehler, MD		
	"Although I have performed robotic cases, I don't feel its benefits outweigh the importance of adhering evidence based medicine and responsible stewardship of health care resources. Thus far the demand for robotic surgery has been largely driven by Intuitive Surgical the makers of daVinci and the uninformed public. Allowing industry and the public to set health care policy is a recipe for disaster, and an unaffordable disaster at that. The clinical data thus far has not been able to clearly or reliably demonstrate improved outcomes yet its expensive is much higher. Personally I think that these robotic cases should only be covered by insurance if they are part of a research protocol evaluating the effectiveness and clinical outcomes. That way cases are concentrated at high volume	*Thank you for your comment.* *No changes to draft report.*

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	centers, minimizing risks to patients, and the robotic wave will not propagate in the absence of data at the expense of precious health care resources based upon corporate greed and public misinformation."	
Baiya Krishnadasan, MD, FACS (Franciscan Health System)		
	"I am a general thoracic surgeon at St. Joseph Medical Center in Tacoma, Washington. I am writing to you regarding your recent call for comments regarding the State of Washington Robotic Surgery HTA. The primary focus of my practice is in the chest, however the issues relating to abdominal surgery can be applied to thoracic surgery as well. I am a strong proponent for robotic surgery. I have incorporated robotics into my practice since 2008 and it has made a large impact in the care of my patients. Specifically the three dimensional visualization and the robotic wristed instruments have made work in the chest dramatically easier and more effective. I have utilized robotics for chest masses, lung and esophageal cancer as well as for benign problems. I have found that patients leave the hospital earlier and recover to their work quicker with the smaller incisions and more precise dissection. I would be happy to share my data with you if you are interested. Patients with larger BMI's are particularly easier to manage with robotics, primarily because of the ability of the robotic instruments to overcome the issues related to chest wall depth and recovery from larger incisions. I strongly discourage your from curtailing the access of patients to robotic surgery. This would be very short sighted and possibly disastrous for some patients."	*Thank you for your comment.* *No changes to draft report.*
David Kummerlow (CADRE, Inc.)		
	"On Feb. 1, 2012 I underwent mitral valve repair under the expert care of Dr. Siwek using the robotic (DaVinci) method. I did not approach the surgery lightly and only scheduled it after multiple consultations with other physicians and hours of research. The results of my research and discussion with another patient who had undergone the same procedure gave me confidence I was making the correct choice. Dr. Siwek and my local cardiologist Dr. Rodrigues screened and tested me carefully to insure I was a good candidate for this procedure.	*Thank you for your comment.* *No changes to draft report.*

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	The surgery was flawless and my recovery timeline fast: 1 day, discharged from ICU, short walks 2 days, discharged from hospital to a nearby hotel 4 days, 1 hour walk inside the Spokane Mall 7 days, driving and in my home office doing light work and emails 12 days, working 1/2 days, attending meetings with clients, regularly walking 1 to 2 miles 3 weeks, flew to California on college visits with our son 4 weeks, back at work full time including an out of town driving trip My wife is a Physical Therapist with over 30 years of ongoing experience including treating patients who have undergone the more traditional sternotomy. During my recovery she would frequently compare how much faster I was returning to a normal life compared to her patients who had "the big zipper". I would recommend that anyone who requires this type of surgery strongly consider having it done through the robotic method under the care of an experienced surgeon like Dr. Siwek. Compared to the traditional sternotomy method my hospital stay was shorter, recovery time considerably faster and I had no complications to speak of. As a self employed individual, it was very beneficial for me to get back to work quickly. As a devoted husband and father of 3 I am just glad to be healthy and able to write this quick note to you."	
Roque Lanza, MD, FACOG		
	"As an Obstetrician Gynecologist for the last 32 years I have seen the evolution of laparoscopic surgery from a diagnostic procedure to what it is now. Robotic assistance needs to be viewed as an evolutionary development of laparoscopic surgery. It is a fine instrument that allows better dissection techniques, visualization and more precise surgery. It will allow more procedures to be done laparoscopic ally that would otherwise been done with laparotomy. The benefits of minimally invasive surgery over laparotomy are not disputed by any study or survey. I remember when laparoscopic cholecystectomies were considered too costly and time consuming …They are now the standard of care. In my practice, I have all but eliminated open laparotomy by developing my laparoscopic skills over	*Thank you for your comment.* *No changes to draft report.*

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	the years including robotic assisted surgery. I truly believe the "long" learning curves discussed in comparing traditional laparoscopy with robotic assisted laparoscopy, reflects an individual's surgical skills with the procedure ,not necessarily learning to do traditional laparoscopy or robotic assisted surgery. By restricting the use of robotic assistance in selective patients you would be preventing the surgeon from using the best instrument available to perform a specific surgery safely. It doesn't make sense. Cost effectiveness is hard to measure, at times it may take common sense. Think of the evolution of transportation; Horse and buggy…Bicycle… automobile..airplane …space craft. Would these have evolved if cost effectiveness were the only measure?. "	
Thomas Lendvay, MD FACS		
	"I am a pediatric urologist at Seattle Children's Hospital and provide laparoscopic and robotic surgery options to my pediatric patients. Many of these children are covered by Medicaid. I have been committed to offering the less invasive robotic approach for historically open surgeries because I have witnessed dramatic reductions in hospital stays times, post-operative narcotic use, and more rapid return to school/daycare in the robotic patients compared to the open cohorts for ureteral reimplantation and pyeloplasties (birth defect surgery to correct urinary reflux and blocked kidneys, respectively). I feel that being able to provide children with the open and robotic options of surgical approach ensures that certain patient populations will not unnecessarily experience higher morbidity and convalescence just because their healthcare is funded by the state. Such a scenario would be in my view socially discriminatory. I understand the need for the state to reign in healthcare costs, however, I oppose eliminating the option for certain patient populations to undergo less invasive surgery."	*Thank you for your comment.* *No changes to draft report.*
John Lenihan Jr., MD (University of Washington School of Medicine)		
	"I would like to provide feedback and comment on the issue you are studying regarding robotic surgery. I have been performing robotic surgery since 2005 and have become a staunch supporter of this advanced technique of performing minimally invasive surgery. The utilization of computers and	*Thank you for your comment.* *No changes to draft report.*

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	surgical robots is a game changer for surgeons. This is clearly the way we will be f=performing almost all surgeries in the future. The utilization of computers will not only enable us to perform more precise and less invasive surgeries with better outcomes for patients, but will also enable us to utilize computer simulation for future training and for the validation of surgical competence. The thought of going backwards and subjecting patients to traditional large incisions with prolonged recoveries and the potential for chronic disabilities afterwards seems similar to the argument that we should go back to horses and carriages and forgo modern modes of transportation."	
	"There have been clear recommendations to utilize minimally invasive surgery approaches to hysterectomy.[1,2,3] Despite over 100 years of vaginal hysterectomies and 23 years of Laparoscopic hysterectomies,12 over 66% of all hysterectomies are still done using a traditional open approach.[4,5] Reasons for this are predominantly lack of training and perceived difficulty of performing both vaginal and laparoscopic approaches.[6,13] Robotic surgery is simply computer assisted laparoscopic surgery. The computer allows significant improvements in surgeon vision (3-D HD instead of 2-D), increased dexterity (full articulation equivalent to the human hand compared to no articulation of instruments using "straight sticks," and smaller less painful incisions (due to the remote centers of the laparoscopic trocars that done pull or stretch like traditional laparoscopic trocars do.[7] Second, Physicians are not paid any more for using this advanced system of laparoscopy. Hospitals have been able to add a "surcharge" for this technology, but not all payors will reimburse this. Third, the outcomes are clearly improved in a variety of ways. Patients recover faster and with less pain.[8] This is hard to prove in randomized trials because they haven't been done yet (Robotic technology was only approved for GYN use in 2005.) There is also substantial benefit to the surgeon with improved ergonomics when compared to laparoscopic and vaginal surgery resulting in far less orthopedic and musculoskeletal complaints.[9,10] The main impact of this technology has been to reduce the open incision rate for traditional procedures to very low rates. Prior to the introduction of robotics, almost all prostatectomies were done through open incisions despite over 15 years of experience with laparoscopic approaches. In 2011, over 85% of all of the prostatectomies done in the USA were done with a robotic approach. This allows a much faster recovery with much less morbidity for the patient than the traditional approach. Hysterectomies are the second most common operation done in this country. As noted above, the rate of Open hysterectomies (Total Abdominal Hysterectomies) in the USA is still 66% despite over a hundred years experience with vaginal hysterectomy and twenty years experience	*Thank you for your comment.* *References provided do not meet inclusion criteria based on study design, outcomes, and availability of references. See Notes section for exclusion criteria. No changes to draft report.*

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	with Laparoscopic hysterectomy.[4,5] In our hospital system, we have lowered the open hysterectomy rate to less than 10% utilizing robotic approaches. This approach enables surgeons who don't feel well enough trained to perform laparoscopic hysterectomies or who can only offer vaginal hysterectomies to a few of their patients to now offer a minimally invasive approach to almost all of their patients. The cost saving of robotic hysterectomies compared to abdominal hysterectomies are substantial. And when you include the societal benefits of patients returning to normal and to work months sooner, there is even greater cost benefit noted. In 2011, there were more robotic surgeries performed in the USA than vaginal and laparoscopic put together. And as computer assisted surgeries continue to evolve and improve with newer innovations, this will only increase."	
	"The risk of complications with robotic surgery has been shown to be significantly lower than the risk with abdominal surgery in multiple studies. The risk is comparable to laparoscopic surgery (1.3-3%). The risk of complications has been shown to be higher during the surgeon's learning curve for robotic surgery, but approaches acceptable levels with experience. The main morbidities of abdominal surgeries include excessive blood loss, wound infections, and prolonged hospital stays. The main risks of laparoscopic and robotic surgeries include vaginal cuff issues such as separation and dehiscence (up to 1.5%) and ureteral injury (1%). Blood loss, vaginal cuff infections and prolonged length of stay are all significantly reduced with robotic surgery compared to open surgery.[14] "	*Thank you for your comment.* *References provided do not meet inclusion criteria based on the study being superseded by a systematic review. See Notes section for exclusion criteria. No changes to draft report.*
	"Robotic surgery has substantial benefits in Obese patients when compared to open, laparoscopic or vaginal surgery.[17] Multiple studies have shown less complications, less blood loss, and lower overall hospital stays with faster return to normal when compared to open surgeries. We presented a paper at the Pacific Coast OB-GYN Society in 2010 showing our results with morbidly obese patients to be equivalent to outcomes with normal weight women with the only parameter that was significantly different was increased blood loss in the morbidly obese group.[18] This difference however was less than 50 cc's and not clinically significant. There have only been published studies comparing robotic to laparoscopic and vaginal surgeries; and these have usually included cases performed during the learning curves of the surgeons. Robotic learning curves have been reported to be 50-100 cases for OB-GYNs and 150-200 cases for urologists. Outcomes for cancer patients are similar to open procedures when considering ability to resect all of the visible disease and obtain adequate lymph node sampling. Future developments utilizing fluorescent imaging technology (only available on robotic platforms) will provide even more precise surgeries that cannot be accomplished using	*Thank you for your comment.* *References provided do not meet inclusion criteria based on study design, and availability of references. See Notes section for exclusion criteria. No changes to draft report.*

Reviewer	Comment	Disposition
	traditional techniques such as open or laparoscopic approaches that aren't capable of this advanced ability to see diseased tissue. There is no particular age or gender benefit for robotic surgery since computer assisted surgery is more precise and less invasive for all ages and genders. Regarding benefits to payors, workers who are able to return to the work force weeks and months sooner due to the significantly lower recovery times required for robotics are clearly beneficial to the payors bottom line and to the economy as a whole. [8] "	
	"There are mixed studies on cost-effectiveness of robotics compared to other modalities based on the methodology of the studies. Most studies published look at direct OR Costs. The primary cost of surgery is OR's time; and there is a long learning curve for robotics, so operative times are usually much longer. If indirect costs are also calculated (cost of the entire hospitalization), the robot does better since robotic patients require less post op care, less medications, have less complications, and are discharged sooner. If societal costs are included, the robot is the clear winner due to the significantly shortened recovery period and faster return to normal. [15,16] "	*Thank you for your comment.* *References provided do not meet inclusion criteria based on comparator/intervention, and availability of references. See Notes section for exclusion criteria. No changes to draft report.*
Brian E. Louie, MD, FRCSC, FACS (Swedish Cancer Institute and Medical Center)		
	"I read with interest the health technology assessment on robotic assisted surgery since we are one of the only groups in Washington State to use the robotic for thoracic surgery. Overall, I thought this was an excellent review of the current status of robotic surgery across all surgical specialties and procedures. It confirms my impression as well as my group's impressions that there is preciously few comparative studies particularly in the newer specialties now accessing the robot. From a thoracic surgery standpoint, I think the evaluations of robotic lung resection, robotic thymectomy, fundoplication and myotomy for achalasia were all appropriate. For lung and thymus, there is little evidence for robotic surgery as of the data of this review. However, for lung resection there are several comparative reports forthcoming this year including our own comparison with VATS lobectomy that will be published in the Annals of Thoracic Surgery later this year that are	*Thank you for your comment.* *No changes to draft report.*

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	starting to highlight the benefits. Clearly, more information is required to confirm oncologic benefit and cost comparisons. For thymectomy, our initial evaluation, which was cited in the references and clearly is an early analysis continues to show benefit, has continued to be correct with the average length of stay now about 1.25 days and a return to work by the patients within 10 days. In my opinion, for the areas like ours where there is little comparative data, robotic surgery should be covered with conditions. I think ongoing assessment of the data will be key in determining payment. I don't think that there should be any additional payment for robotic surgery since it remains a platform to conduct an operation. Providers like us who are at the forefront of technology and care and who are reviewing our data and outcomes should have the opportunity to show how we have used the robotic to improve the outcomes of patients, shortening LOS and get the patients back to work sooner. Congratulations on an excellent review."	
John Luber, MD, FACS		
	"I have been a cardiac surgeon in practice for 31 years. Over half of my career has been spent in academics, from Asst Professor to Chairman of the largest academic program in New York, Albany Medical College, from 1994 to 1998. I have reviewed both the outcomes in robotics in CT surgery as well as the opinions from the current RUC Chair. There appears to be only marketing and no demonstrable improved outcomes for a substantial increase in cost and an unacceptable learning curve. I believe that robotics deserves close study in the academic environment but is currently a technique in search of an indication. It should be supported for study but not for routine patient care in any specialty. No acceptable outcomes studies demonstrating superiority exist."	*Thank you for your comment.* *No changes to draft report.*
Gordon L. Mathes, JR., MD (Rocky Mount Urology Associates)		
	"I am an urologist in North Carolina. I perform robotic prostatectomy and robotic partial nephrectomy, among other robot-assisted procedures. There is NO question at all that the surgical robot enhances outcomes for my patients. Surgical blood loss, which is decreased by 90% with the use of robotics, is enough of a reason BY ITSELF to prove the superiority of the robotic technique."	*Thank you for your comment.* *No changes to draft report.*

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Patris Marandi, MD (Providence Everett Medical Center)		
	"I have recently started to perform Robotic assisted colon surgery and cholecystectomy. In have 10 years plus experience in laparoscopic colon resection and much longer experience with other laparoscopic abdominal surgeries. In Robotic assisted colon surgery, I have seen decrease in length of stay by one to two days in comparison to laparoscopic colon resection and less narcotic pain medication use. In regards to Robotic cholecystectomy, my patients have required less narcotic pain medication in comparison to laparoscopic cholecystectomy. I see great advantage in use of Robotic surgery in all colonic surgeries specially in rectal tumors and upper abdominal surgeries(such as Nissen funduplication) so far. I encourage you to allow this technology to be offered to all patients equally."	*Thank you for your comment.* *No changes to draft report.*
Heather Miller, MD (Swedish Medical Center)		
	"I understand that there is a comment period regarding coverage of robotic surgery? The vast majority of the hysterectomies and myomectomies at our institution are done robotically. This has been a revolution in gyn surgical care. Prior to the robot (2005/2006) most of these procedures were being done through large laparotomy incisions. There is no question that the morbidity from a laparotomy incision is much greater than that from a laparoscopic/robotic procedure. The hospitalization is less than 24 hours in many cases and recovery is in the 2 - 4 week range as opposed to 6 - 8 weeks. Many surgeons are not trained to perform hysterectomy or myomectomy with simple laparoscopy ie without the robot. Laparoscopy without the robot assist would not be a reasonable alternative/option in most cases because the surgeon would not be able to do the case without the robot. Covering laparoscopy but not robotics would basically limit the patient to laparotomy in most cases. Robotically assisted laparoscopy should be covered."	*Thank you for your comment.* *No changes to draft report*
Karen Nelson, MD		
	"I want to voice my strong concern that reimbursement for robotically assisted minimally invasive surgery may be eliminated for certain patients, including state employees and Medicaid patients. I have been performing robotically assisted gynecologic surgery since 2005. Prior to that, I performed	*Thank you for your comment.* *No changes to draft report*

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	minimally invasive surgery vaginally and laparoscopically. Studies are clear that many advantages accrue to patients who undergo minimally invasive surgery including shorter hospital stays, shorter recoveries and quicker return to work. Minimally invasive surgery also reduces the risk of adhesion formation. Adhesions may result in pain and/or bowel obstructions necessitating additional surgeries. In some cases, minimally invasive surgery can be performed vaginally or laparoscopically. However, robotically assisted surgery is especially well suited for patients with higher body mass indices (obese patients), patients with prior surgeries and patients with enlarged uteri. Many of these patients would require a large abdominal incision if robotics were unavailable. Higher hospital costs are associated with open procedures, as are greater risks of wound infection and adhesion formation. This is an injustice to the patient."	
Kerilyn Nobuhara, MD, MHA (Senior Medical Consultant, Washington Health Care Authority)		
	"Here is my initial draft for the agency comments on this OHSU report. I was disappointed with the overall quality of the report, but this is probably more reflective of the lack of medical evidence in general for robotic assisted surgery. I will probably add some additional commentary about the meta-analyses performed for this review."	*Thank you for your comment.* *No changes to draft report*
	"This report highlights the absence of high quality medical evidence addressing the impact of robotic assisted technology on clinically meaningful surgical outcomes. The best available evidence confirms that robotic assisted technology is associated with higher costs per procedure per patient. The report does not emphasize that robotic assisted surgery must only be considered in the context of the standard (open or laparoscopic) approach itself being supported by medical evidence. Robotic assisted surgery is a method of performing a surgical procedure and is a matter of choice of the surgeon. At present, robotic assisted surgery is not treated as a separate service by the American Medical Association, but is considered incidental to the primary surgical procedure, and therefore not separately billable. While this report attempts to consider robotic assisted technology as a separate service, by structuring the key questions around different surgical procedures, the actual determination of the medical necessity and impact of this specific technology on meaningful clinical outcomes is problematic at best. Another key point which is undermined in this report is that the robotic assisted technology cannot equilibrate technical or decision making skills among different surgeons, and therefore, as is the case for all procedure based clinical studies, the widespread	*Thank you for your comment.* *No changes to draft report*

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	applicability of outcome measurements cannot be assessed. With individual surgeon expertise as the primary confounding variable, many of the evidence ratings require further scrutiny."	
	"p. 2 "Many procedures are associated with increased complexity, operative times, and technical difficulty when attempted laparoscopically, and open laparotomy approaches are the current standard of care." This statement is incorrect, and for several surgical procedures a laparoscopic approach rather than an open laparotomy is the established standard of care. This baseline assumption leads to several incorrect comparator selections for this report, which are highlighted below."	*Thank you for your comment.* *The Washington HTA identified the comparators used in this report. All comparative studies using either open or laparoscopic procedures were therefore included. This does recognize that, for some procedures, laparoscopy is either not available as a surgical option (i.e. various cardiac and gynecologic surgeries), or extremely difficult to perform (i.e. partial nephrectomy). In these cases, open procedures are the standard of care and, therefore, are the comparator studied.*
	"pp. 5-6 For both the radical prostatectomy and hysterectomy KQ 1 comparators, robot assisted surgery was associated with reduced blood loss and risk of transfusion as compared with the open procedure. Selection bias was not taken into account and these statements are misleading, as these patients were only stratified by tumor grade (p. 31). "	*Thank you for your comments.* *Your concerns are addressed in the overall summary section in the ES and in more detail in the Findings/ Limitations section of individual topics In addition, the overall report summary re-emphasizes the presence of dissimilar comparison groups in many studies.*
	"pp. 7-15 Highlight a general lack of evidence regarding the use of robotic assistance in various surgical procedures. However, the amount of discussion in the report is not proportional to the	*Thank you for your comments.* *This report was organized in*

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	quality or volume of evidence. We recommend that the findings be summarized in a table, listed by procedure and prioritized by the associated strength of evidence: prostatectomy, hysterectomy, nephrectomy, cardiac surgery, gastric band, adnexectomy, adrenalectomy, cholecystectomy, colorectal surgery, cystectomy, esophagectomy, fallopian tube reanastomosis, fundoplication, gastrectomy, ileovesicostomy, liver resection, lung surgery, myomectomy pancreatectomy, pyeloplasty, rectopexy, roux-en-Y Gastric bypass, sacrocolpopexy, splenectomy, thymectomy, thyroidectomy, vesico-vaginal fistula."	*concert with the work plan developed for the Washington HTA. Reports on over 25 procedures were reported individually addressing all of the key questions. We will consider this recommendation for the clinical committee presentation.*
	"p. 32 The report states a "significant heterogeneity" was present between meta-analysis studies, yet a pooled meta-analysis was performed. Given the heterogeneity between studies we question the rating of a "moderate strength" of evidence. This comment is highlighted again on p. 35, "The quality ratings of the studies, which were observational in design, varied. The choice of patient participation in the treatment arms was subject to selection bias. Those in the robotic intervention arm frequently were younger, had less advanced tumors, and lower PSA baseline scores." "	*Thank you for your comments.* *"Moderate strength of evidence" is defined in detail on page 29 of the report. It is based on the GRADE system. Systematic heterogeneity was investigated and reported by CADTH and CEbP..*
	"p. 43 "Robotic prostatectomy is compared with a laparoscopic approach", this is a typographical error, it should be hysterectomy rather than prostatectomy."	*Thank you, typographical error corrected.*
	"p. 43 The report states that robotic-assisted radical hysterectomy compared with laparoscopic radical hysterectomy is associated with a lower complication rate. However, on p.41 the report states that "inconsistent results were reported for incidence of complications across all meta-analyses." These two statements appear to be conflicting, and clarification is requested."	*Thank you, typographical error corrected.*
	"p. 49 The meta-analysis of pooled data with significant heterogeneity between studies was again utilized to generate the conclusion that weighted mean difference was significant in favor of robot assisted partial nephrectomy in terms of shorter length of hospital stay, at -.25 days, compared with laparoscopic partial nephrectomy."	*Thank you for your comments.* *As noted above, systematic heterogeneity was investigated by CADTH and the CEbP. In addition, Table 5 is preceded by the qualifier "In general, there was consistency across most meta-analyses for the*

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		following outcomes: hospital stay, incidence of complications, blood loss, and incidence of transfusion."
	"p. 112 "Guideline Recommendations Summary" table should be titled "Guideline Summary." The "Quality" of the guideline is unclear. Is this the quality of the evidence on which the guideline is based? On what basis was this determination made?"	*Thank you for your comments.* *This table has been renamed as suggested. The guidelines were quality assessed (pg. 30) using an adapted instrument from the Appraisal of Guidelines Research and Evaluation (AGREE) collaboration. The instrument is provided in Appendix G. The quality of the guidelines is stated in the text. The AGREE instrument takes into account the rigor of development of the guideline which includes systematic methods were used to search for and include evidence.*
	"The report mentions repeatedly the "lack of definition" of an experienced robotic surgeon. Without evidenced-based determinations to establish a minimum case volume requirement in order to achieve competency, we would reiterate that the pooled meta-analysis technique used by this report is fundamentally flawed. If outcome measurements are so clearly associated with the level of experience of the robotic surgeon and center, then insufficient evidence is available to answer key question #2, regardless of the associated surgical procedure."	*Thank you for your comments.* *None of the meta-analyses in this report were stratified by surgeons' experience. This was amplified (addressing overall conclusions specifically regarding key question #3) in paragraph 1, pg. 115.*

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Steve Poore, MS, MD, FACOG (Women's Clinic-MultiCare Northshore Clinic)		
	"I have been in woman's healthcare for approximately 25 years. As an obstetrician gynecologist I have seen the transition from traditional open laparotomy, to the laparoscopic, and now Robotic minimally invasive approach. Having reviewed the draft evidence report submitted together with the cost analysis versus benefits realized, it becomes clear the focuses on upfront costs is playing a major role in the direction of this discussion. One area of conversation that has been grossly overlooked is the reduction of pain experienced by the patient. As a direct result of the lower pain and shortened recovery, the patient's return to normal activities is markedly reduced. This important point has resulted in a reduction of recovery interval from what was originally 4-6 weeks for major abdominal surgery(i.e. hysterectomy), 2-4 weeks for minimally invasive straight laparoscopic/vaginal hysterectomy, to what is now seen routinely for robotic surgery: 2 weeks for return to normal activities. Clinical examples are numerous; one that comes to my mind involved a hard working woman whose job was driving an 18 wheel truck cross-country. Surgery was clearly in her best interest and on reviewing the options, return to normal activities(to include work) was paramount in her choice. I'm happy to report her surgery proceeded uneventfully. She returned to full activities in less than 2 weeks; earlier than any other operative approach would've allowed. Examples of clinical outcomes as we are reviewing here are important, and I encourage its continued review and process. Unfortunately to overlook the implications of reduced pain and return to normal activities grossly under estimates value of this surgical approach: Robotic surgery. As everyone is already aware, use of the da Vinci robotic approach results and no additional compensation to the surgeon or the institution. In my practice, transition from abdominal approach to laparoscopic and now Robotic approach is for more reasons than just cost. Better clinical outcomes which already have been indicated in your monologue. In addition a reduction in pain experienced with a much quicker return to normal activities for patients. I would hope that in the final analysis, implementation of new technology in an effort to provide superior outcomes and quicker return to normal activities for our patient's is not ruled out for certain covered individuals based on a cost analysis by given insurance plan. Reimbursement policy regarding da Vinci robotic surgery as we all know, results in no additional	*Thank you for your comment.* *No changes to draft report.*

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	reimbursement to the physician or cost to the insurance plan over that of straight laparoscopic approach. It is for OUR patients benefit we accept the undervalued reimbursement, for the improved wellbeing of the patient and their earlier return to normal life activities."	
James Porter, MD; Todd Strumwasser, MD; and Mary G. Gregg, MD, MHA (Swedish Medical Center)		
	"This letter contains comments and recommendations on behalf of The Robotics Committee at Swedish Health Services (SHS) in response to the Health Technology Assessment draft evidence report (HTA) for Robotic Assisted Surgery (RAS). We commend the efforts that have been undertaken by this HTA. In support of continually working to improve patient care, our comments are as follows: **JUSTIFICATION OF INTERESTS** SHS currently has the largest robotics program by volume and specialty within Washington State. Established in 2005, the program has grown each consecutive year, and performed over 1,3000 RAS cases in 2011. The program currently operates at 4 SHS campuses, First Hill, Cherry Hill, Edmonds, and Issaquah, with physicians practicing in the following disciplines: • Urology • Colorectal • General • Gynecology • Gynecologic Oncology • Otolaryngology • Thoracic • Cardiac Surgery SHS has developed and implemented an extensive administrative framework to support a sustainable robotics program that strives to deliver high quality, appropriate care, in an efficient environment. As the program has evolved, SHS and affiliated providers have raised many of the same concerns contained within this HTA. SHS has effectively mediated many of these concerns through collaborative efforts between surgeons, staff, management, and vendors. These efforts include standardized credentially of physicians and allied health providers seeking privileges for robotic surgery, ongoing quality assessment of robotic surgical procedures, and data collection of robotic surgeries for research and publication.	*Thank you for your comment.* *No changes to draft report.*

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	COMMENT 1 In response to the HTA's recognition regarding the low volume of literature related to RAS, RAS is a relatively new surgical procedure. Published literature often is many years behind new technology. A key example of this was with the adoption of laparoscopic surgical techniques. While the use of laparoscopy and other minimally invasive methods are now commonly accepted as the standard of care, at their inception, literature supporting their use was lacking. RAS, especially as a subset of minimally invasive technique, has unfolded in the same manner. The current literature cited by the HTA compares an immature experience with RAS with a mature experience in open and laparoscopic techniques. This makes meaningful comparison between techniques challenging especially at this early stage in adoption. **RECOMMENDATION 1** In light of the HTA's recognition of the limited volume of literature related to RAS, further study and data related to RAS must be generated before meaningful comparisons can be made to current treatment standards. Furthermore, at this time there is no data to suggest that RAS is unsafe or compromises patient care. SHS requests that the analysis continue until sufficient literature exists. At such time, the HTA can effectively generate recommendations related to the efficacy of the modality as a whole.	*Thank you for your comment.* *No changes to draft report.*
	COMMENT 2 Improved outcomes associated with RAS has been recognized in centers where a high volume of surgery is routinely performed. Several studies have shown that the greater the experience of the surgeon performing robotic procedures, the better the overall outcomes. Experience of not only the surgeon is important, but also of the nursing staff, anesthesia staff, and ancillary care team. This would suggest that centers that perform a high volume of RAS would be the most efficient and provide the best quality of care. This model has proven successful in other care disciplines such as stroke and trauma where regional centers of excellence are created to facilitate best practices and provide the highest level of care. SHS has grown to become the regional leader in RAS and has more experience providing RAS procedures than any other center. The organizational structure of our RAS program has allowed ongoing assessment of RAS quality measures such as length of stay, blood loss, operative time, and complication rate. These outcomes are reviewed by our Robotics Steering Committee and	*Thank you for your comment.* *No changes to draft report.*

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	recommendations are made to improve outcomes for each specialty performing RAS. Each specialty performing RAS has maintained on ongoing collection of data for review and publication. This allows improvement in RAS by assessing outcomes. Finally, SHS has also taken an active role in training other surgeons from across the country in RAS. **RECOMMENDATION 2** Regional data regarding RAS and its comparative efficacy to open surgery can be obtained from regional centers of excellence. This data it would be more meaningful in making recommendations for RAS in the state of Washington. Our recommendation is that HTA work with high volume RAS centers to obtain quality data for assessment and determination of future scope of robotic surgery practice in our state.	
	COMMENT 3 Currently there are additional costs associated with performing RAS procedures. However, the cost to the state of Washington for RAS is the same charges as the laparoscopic procedure given the equivalent CPT codes for robotic and laparoscopic surgery. There is no additional charge to insurance company's or the state for robotic-assisted procedures. The increased capital costs associated with robotic surgical systems have been incurred by hospital systems in an effort to provide patients with state of the art surgical care. In addition, studies that look at operating room costs do not take into account the cost savings created by shorter length of hospital stay which has been clearly demonstrated in multiple studies of RAS. The economic advantage to employers when a patient is able to return to work sooner after RAS as compared to open surgery is difficult to measure, but represents a downstream advantage of RAS over conventional surgery. **RECOMMENDATION 3** Cost analysis of RAS versus open or laparoscopic surgery should include the savings associated with shorter length of stay and earlier return to work.	*Thank you for your comment.* *No changes to draft report.*
	COMMENT 4 Operative times associated with RAS are by in large longer than the open surgical counterpart in the initial experience of robotic surgeons. This is related to increased time associated with gaining	*Thank you for your comment.* *No changes to draft report.*

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	minimally invasive access to the body. However, with experience the RAS procedure approaches the operative times associated with the open surgical procedure. In our experience with RAS at SHS, the operative times associated with high volume procedures such as prostatectomy and hysterectomy are now equivalent to the open surgical times and in some cases faster. There is one RAS procedure that has demonstrated faster operative times than the open counterpart from the beginning and this is trans-oral surgery for base of the tongue cancer. This use of RAS is not only more efficient than the open procedure but is less morbid for the patient and leads to better functional outcomes. **RECOMMENDATION 4** With increasing experience, the costs associated with longer operative times in RAS procedures will decrease. Therefore, further study should be undertaken in high volume RAS centers to determine the true cost of the procedure as it related to operative time."	
Charles Richards, MD (Pullman Regional Hospital)		
	"I am an OB/GYN who has been recently been trained in robotic surgery. I have been very impressed by the advantages that robotic surgery offers both for me and my patients. The advanced optics allow me to see anatomical structures that I would not otherwise see at surgery, and allows me to operate more precisely. I must say that I have been impressed by the lessened pain and quicker discharge of patients from the hospital as a result of this. Blood loss is extremely minimal and healing is quicker. In a progressive country where patients demand the best, I feel it would be unwise to eliminate robotic surgery as an option for any group of patients. I feel that robotic surgery is here to stay and is a great option for patients considering hysterectomy or other gynecological procedures."	*Thank you for your comment.* *No changes to draft report*
Clifford W. Rogers, MD (Minimally-Invasive Gynecologic Surgery)		
	"I have practiced Obstetrics and Gynecology in Everett, Washington since 1988. Since 2006, I have limited my practice to Gynecology. Robotic assisted surgery has become a major part of my Gynecology practice the past 3 years. I have performed over 200 robotic hysterectomies since early 2009. Like most ob/gyn physicians, for most of my career 60% or more of the hysterectomies I performed	*Thank you for your comment.* *No changes to draft report*

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	were done through large abdominal incisions. The majority of these patients had 3-4 day hospital stays and were on disability for an average of 6 weeks while recuperating. Starting in 2004, I committed myself to advancing my laparoscopic surgical skills, and began performing more laparoscopic hysterectomies. These patients were often able to go home in 1-2 days, and some were able to go back to work in 2 to 3 weeks. However, my open hysterectomy rate remained about 40%, as I found that the limitations of standard laparoscopic instruments caused me to have to abandon the laparoscopic approach and convert to an open hysterectomy in a significant number of patients. There were additional patients I would not consider for laparoscopic hysterectomy because of anticipated surgical complexity due to obesity, multiple prior laparotomies, larger fibroids, or severe endometriosis. That has all changed dramatically since 2009 with the introduction of robotic-assisted laparoscopic surgery into my practice. My abdominal hysterectomy rate has declined to 5-10% per year the past 3 years. This has made an enormous difference for my patients. Many are discharged from the hospital on the day of surgery, the remainder are routinely discharged after a one night stay. Most of my patients return to work, school, or their other normal activities within 3 weeks. My complication rates have been very low. For example, none of my 200+ robotic hysterectomy patients have required a blood transfusion. Only 1 patient has required re-admission to treat a post op infection. Many of these robotic-assisted surgeries have been complex surgeries due to multiple prior abdominal surgeries, obesity, diabetes, and other risk factors. With the exception of massively enlarged fibroid uteruses or large pelvic masses, I find that the capabilities of the robotic instrumentation allows me to operate with more safety and precision than open abdominal surgery. In summary, the advantage of robotic-assisted laparoscopic surgery (in my experience) is that the improved instrumentation and capabilities of the robotic platform allows me to avoid an open laparotomy incision in a much higher percentage of my operative patients, perform more complex surgeries more safely, dramatically decrease hospital stays, and allow the majority of my patients to return to work and other normal activities much earlier.”	

Reviewer	Comment	Disposition
Dennis W. Shook		
	"The entire surgical process is viewed, by many, as cold and impersonal. Adding a "Robot" to the scenario will only enhance this opinion to many. Furthermore there is no overall conclusive evidence or opinion that robotic assisted surgeries improve the surgical outcome for the patient. It should be an elective, but , not covered option for the patient"	*Thank you for your comment.* *No changes to draft report*
Leland Siwek, MD (Providence Sacred Heart Medical Center)		
	"I would like to take this opportunity to provide some input regarding the effectiveness and benefits of robotic assisted open heart surgery. I am a practicing cardiac surgeon with extensive personal experience with robotic open heart surgery, having one of the largest experiences with robotic mitral valve surgery in the country. Having trained in the 1980s and being a practicing heart surgeon for 25 years I of course am well aware that conventional open heart surgery via a sternotomy has been the "gold standard". That said I also see that this major life-saving surgery is hard on patients and we have to strive to make that better. Our own interest in robotic assisted heart surgery began as an attempt to make mitral valve surgery better tolerated and more acceptable to patients, hopefully without compromising the excellent results which could be achieved with conventional techniques. We began conservatively with selective cases but soon realized that the robotic approach has definite advantages and the outcomes are even better than with standard approaches. Our initial efforts to do minimally invasive mitral valve surgery were via a mini-thoracotomy endoscopic approach. While this had some advantages it was technically difficult and more importantly not as reliably predictable as we would want. Some cases were simply too difficult to complete that way. We hoped, and subsequently found, that the assistance of the robot with its enhanced instrument dexterity and magnified 3-D vision would make the procedure much more predictable and reliable. We began doing robotic mitral valve surgery at Sacred Heart Medical Center in 2003. We began with more simple, predictable valve repairs but gradually realized that we were able to repair much more complex valves *even better* than we were doing via conventional open surgery! Now when we see complex mitral valve pathology we feel significantly more confident approaching that repair	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	robotically than via other techniques. I think our results over these years indicate the excellent outcomes which can be achieved via a robotically assisted approach. The following results include our very earliest "learning curve" cases and cases done with the first generation of robot. The current robotic system, along with our experience, has made the recent results even better. From June 2003 through March 2012 we have performed 461 robotic assisted mitral valve repair operations and 55 robotic assisted mitral valve replacements. All but one of the valve replacements were planned pre-operatively to be replaced (usually due to rheumatic pathology) with only *one* patient converted from planned repair to replacement. While the cardiopulmonary bypass times are somewhat longer the overall operative times are similar to conventional open procedures and the outcomes are outstanding. I recently summarized our results with mitral valve repair for a book chapter I've been asked to write, I will copy that summary here: Between June 2003 and June 2011 we performed 410 robotic mitral valve repairs. (During that same time we performed 53 mitral valve replacements usually for rheumatic valve disease). 61.5% of patients were males and mean age was 59 +/- 13 years (20-86). The repair techniques included leaflet resection (63%), sliding leaflet reconstruction (20%), Gore-Tex suture (W.L.Gore & Assoc. Inc, Flagstaff, AZ) neo-chordae (18%) and isolated ring placement (17%). Concomitant procedures included closure of left atrial appendage in 63% of patients, closure of PFO or ASD in 26% of patients, and Cryo-Maze procedure in 17% of patients. Concomitant robotic CABG was performed in three patients. In this series of 410 consecutive robotic mitral valve repairs there were only two conversions from robotic to open procedure: an 80 y.o. woman who developed an aortic dissection immediately upon institution of cardiopulmonary bypass and a 77 y.o. woman converted to sternotomy at the end of the procedure to control bleeding from the aorta. There was one operative mortality (the patient with the aortic dissection). There was one conversion from planned repair to replacement (a remodeling annuloplasty ring placement for "functional" mitral regurgitation that still had 2+ MR). Total cardiopulmonary bypass time was 143 +/- 29 min and cross clamp time was 99 +/- 21 min. Both of these times have trended down over the course of our experience despite increasing complexity and frequency of concomitant procedures. During the last two years the cardiopulmonary bypass and cross clamp times were 121 +/- 19 min and 84 +/- 16 min for mitral valve repair without Maze	

Reviewer	Comment	Disposition
	procedure and 164 +/- 44 min and 101 +/- 21 min with concomitant Maze procedure. Post operative TEE showed 0 or trace MR in 98% of patients and no more than 1+ MR in any patient. There were four (1%) perioperative strokes, and 2% reoperation for bleeding (0.5% the last two years). Hospital length of stay was 4.0 +/- 2.5 days. Two patients required early reoperation, one for endocarditis and one for delayed aortic dissection. Five patients have required late reoperation, two for endocarditis, one for dehiscence of a rigid ring, one for mitral stenosis 6 years after quadrangular resection, and one for ruptured Gore-Tex chordae. As you can see these are truly outstanding results with >99% successful valve repair. At least in our experience this is significantly better than we were achieving previously with open conventional techniques. While shorter recovery times are important considerations for minimally invasive surgery we believe the most important priority in mitral valve surgery is optimizing the likelihood of valve repair and we feel we have definitely achieved that with robotic assisted mitral valve repair. Comparison to open sternotomy is difficult, particularly since the patient benefits (successful repair and improved recovery) seemed so obvious to our regional referring cardiologists that they send all mitral valve patients to us for a robotic approach and virtually all the mitral valve procedures at Sacred Heart are performed robotically. Since Sacred Heart's mitral valve data reflects primarily robotic procedures and most of the data from the rest of the state is from conventional procedures, comparison of Sacred Heart to the rest of the state in the COPE database gives at least some indication of the relative effectiveness of the robotic approach: [*see page for graphs*] I'm afraid we don't have extensive cost data, but our hospital did audit the results of patients from 2008 and found that open mitral valve procedure patients had an average length of stay of 12 days vs. 4.8 days for those done robotically. The hospital's costs were an average of $51,669 for open procedures vs. $36,483 for the robotic procedures. Based partly on this data as well as patient satisfaction etc our hospital confirmed their commitment to our robotic surgery program. While difficult to quantify, our patients have a definite improvement in recovery time. Hospital length of stay is shorter (most of our patients are discharged 3 days after surgery) but more importantly they are able to return to physical activities much quicker. Not only are they not	

Reviewer	Comment	Disposition
	restricted because of sternotomy healing issues, but they generally feel capable of physical activities quicker. We have had active patients return to sports in weeks, or patients with physically demanding jobs return to work in weeks rather than the 2-3 months they would have to wait for a sternotomy to heal. While difficult to capture this obviously saves employers significantly when their employees can return to full capacity sooner. In addition the robotic approach avoids some of the complications associated with conventional surgery, in particular we obviously do not have any sternal wound infections or healing problems and almost never have even minor port incision healing issues. As you know even an occasional sternal healing problem is a huge issue for the patient and adds significantly to the cost of care. Lastly I'd like to make a couple of comments about other robotic open heart surgery. While our interest and experience has emphasized mitral valve surgery we do have a fairly sizeable experience with other robotic cardiac surgery. We have done 72 ASD closures with excellent outcomes and the patient benefits of avoiding a sternotomy. This has become our preferred approach to remove atrial tumors – we have done 22 of these procedures in the past few years. We don't have as much experience with totally robotic coronary bypass (TECAB) as a few other centers in the country but have performed 52 TECABs with average length of stay of 3 days and angiographically confirmed LIMA graft patency in all patients! In summary, I believe that robotic technology is a useful tool which allows an experienced surgeon to offer patients a less invasive approach for certain open heart surgical procedures. In experienced hands the results can be excellent and the patients have the additional benefit of fewer complications and faster recovery and return to normal activities. A hospital such as Sacred Heart which places patient outcomes as the primary priority sees the value of these procedures even though there is significant cost involved. Particularly in a system where the payer is paying based on the procedure performed (eg Mitral Valve Repair) and not based on the surgical approach used, I would hate to see patients told they had to have an open sternotomy and would not be allowed a less invasive approach just because they are dependent on State coverage. I hope you will take these comments into consideration as you reach your coverage decisions."	

Reviewer	Comment	Disposition
Doug Sutherland, MD (MultiCare Urology)		
	"I am writing in response to the upcoming debate on robotic surgery within the WA Health Technology Assessment program. I applaud the effort. Ideally we can move to prospective analysis of medical technology before implementation, but until that day, this process adds value. That said, I am curious why robotic surgery is being reviewed individually given that the payment for state employees and Medicaid made to hospitals and surgeons is for a laparoscopic surgery with no additional sum for the use of the robot. It would be more accurate to assess "laparoscopy" as a whole I believe. Isolating robotic surgery would make more sense if we were paid additionally for it, which I believe is not the case. Much has been said about robotics. There is essentially no level 1 data to support it, which is not surprising. Robotics represents the frontier of surgical innovation, along with single site surgery and natural orifice surgery (NOTES). And since American citizens get to determine 'their' best option, it is unlikely that such RCTs will be done. So, your committee will also be making a judgment on how surgical innovation is delivered - whether or not it can continue in the market place or will be confined to IRB controlled, state/industry funded trials. More to the point, I believe you are making a judgment about laparoscopy vs. open surgery by tackling the issue of robotics. It can no longer be assumed that a patient with a surgical disease can opt between 3 equally good choices: open, laparoscopic, and robotic approaches. The surgeries we perform now with the robot in many cases cannot be performed nearly as well as with a purely laparoscopic approach, it at all. In the field of urology, that is most evident with partial nephrectomy for renal cell carcinoma. As recently as 2006 there is clear evidence from the Medicare data that partial nephrectomy was severely underutilized for tumors that could have been treated in a nephron-sparring manner, thus sparring the patients the risk of longer term renal insufficiency and related sequelae. That has largely been overcome in large part due to the robotic platform. Why? Because when offered the choice between a *laparoscopic radical* nephrectomy or an *open partial* nephrectomy, patients will favor the less invasive, less painful route. The robot levels the field surgically-speaking: those surgeons who can perform a good open partial nephrectomy can do the same with the robot, but cannot with pure laparoscopy. The primary reason that laparoscopic partial nephrectomy is so incredibly difficult to perform is the	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	need for complex laparoscopic suturing skills (the same is true for laparoscopic radical prostatectomy, pyeloplasty, and cystectomy). The learning curve associated with this procedure is incredibly steep and that is why the procedure is isolated to major academic centers in general. Thus, in the case of the small renal mass the alternatives are open partial nephrectomy, which requires a large midline or flank incision; laparoscopic or percutaneous tumor ablation, which requires a longer radiographic follow-up and a higher risk of recurrence and potential need for additional procedures, or laparoscopic radical nephrectomy. We have looked at our institution's length of stay for open, laparoscopic and robotic partial nephrectomy. On average, the robotic patients stay 2.3 days, the open patients stay 6.3 days (see below). No doubt there are practice patterns and pre-operative selection bias that are influencing those numbers, but a flank incision unquestionably more difficult to recovery from, which is why laparoscopic *radical* nephrectomy and cholecystectomy have become the standard of care over the open approach. *MultiCare Urology Partial Nephrectomy stats:* *Open partial (n=3): Blood loss (ave) 533cc, Ischemia time 55.5 minutes, Hospital stay 6.3 days* *Laparoscopic partial (n=5): Blood loss (ave) 200cc, Ischemia time 23.8 minus, Hospital stay 2.2 days* *Robotic partial (n=26): blood loss (ave) 103cc, Ischemia time 22 minutes, Hospital state 2.3 days.* One might look at those numbers and argue that 4 days of hospital stay is not that much savings for the cost of the laparoscopic and robotic equipment for an entire population. That is a rational argument indeed. That however is not an argument against robotics, it is an argument about the cost effectiveness of robotics, which is quite different. Considering that we are not paid additionally for robotics, as I said above, the argument is really examining open surgery vs. laparoscopy, not robotic surgery."	
Kim Tillemans, DO		
	"I practice in Minneapolis, MN. I have come to realize having the ability of robotic surgery helps me operate more accurately.	*Thank you for your comment.* *No changes to draft report*

Reviewer	Comment	Disposition
	Specifically for endomtriosis resection or TLH and myomectomy laparoscopically. It helps me operate with precision with minimal blood loss. I recommend it being available for all patients."	
Renata R. Urban, MD (University of Washington Medical Center)		
	"My name is Renata Urban, and I am a gynecologic oncologist at the Seattle Cancer Care Alliance/University of Washington Medical Center. I am writing regarding the upcoming Health Technology Assessment of Robotic Surgery, currently being reviewed by the Washington State Health Care Authority. I am currently trained to offer patients surgery via an open or minimally invasive approach. My minimally invasive skills are in both laparoscopic as well as robotic surgery. My experience with minimally invasive surgery parallels that of the literature (Seamon LG et al Gynecol Oncol 2009, Bell MC et al Gynecol Oncol 2008, Boggess et al, Am J Obstet Gynecol 2008), in that robotic surgery allows me and my colleagues within the field of Gynecologic Oncology to perform minimally invasive surgery with increased safety. In addition robotic surgery allows me to offer minimally invasive surgery to medically morbid patients, such as the morbidly obese. There are certainly patients for whom I choose to perform laparoscopic surgery, instead of robotic assisted laparoscopic surgery. However, certain patients are much better candidates for robotic surgery. I would like to continue to be able to offer my patients the best treatment possible for them, and to be able to offer robotic-assisted laparoscopic surgery as an option."	*Thank you for your comment.* *No changes to draft report*

Appendix K. Errata

First column refers to page and paragraph number of final report posted to Washington HTA website dated 4/15/12. Second column refers to page and paragraph number of updated final report posted to Washington HTA website dated 5/3/2012.

Final Report Page #/ Paragraph #	Updated Final Report Page #/ Paragraph #	Correction
EXECUTIVE SUMMARY		
3/4	4/3	Reworded strength of evidence ratings for consistency
3/7	4/6	Reworded strength of evidence ratings for consistency
3/9	4/8	Reworded strength of evidence ratings for consistency
4/1	5/1	Reworded strength of evidence ratings for consistency
5/1	6/1	Edited to agree with report body, strength of evidence rating added
5/2	6/2	Reworded for clarity, strength of evidence rating revised
5/3	6/3	Strength of evidence rating moved to KQ 2 as appropriate, edited for clarity
5/5	6/5	Text deleted, moved to next paragraph
5/6	6/6	Edited for clarity
6/2	7/1	Strength of evidence added for additional outcomes
6/3	7/2	Strength of evidence revised
6/4	7/3	Strength of evidence added, edited for redundancy
6/5	7/4	Strength of evidence added, revised for clarity
7/1	8/1	Strength of evidence added, findings added for completeness
7/2	8/2	Strength of evidence revised to match report body, revised for clarity
7/4	8/4	Revised for clarity
7/6	8/6	Strength of evidence and summary added to match report body, revised for clarity
7/7	9/1	Strength of evidence and findings added
7/8	9/2	Strength of evidence revised, edited for clarity
7/9	9/3	Strength of evidence revised, text added for clarity and consistency, non-economic outcome deleted
8/2	9/5	Edited for clarity
8/3	9/6	Strength of evidence added, edited for clarity
8/4	9/7	Edited to match report body
8/7	10/2	Edited to match report body
8/12	10/7	Strength of evidence revised, edited for clarity
9/5	10/12	Edited for clarity
9/9	11/3	Edited to match report body

9/10	11/4	Edited to match report body
10/1	11/5	Edited for clarity
10/2	11/6	Edited for clarity
10/3	11/7	Edited for clarity
10/5	11/8	Edited to match report body
10/6	12/1	Edited for clarity, strength of evidence added
10/8	12/3	Edited for clarity
10/9	12/4	Text deleted due to redundancy
11/4	12/8	Edited for clarity
12/2	13/8	Edited for consistency and clarity
12/5	14/1	Edited to match body of report
12/7	14/3	Edited for clarity
12/8	14/4	Strength of evidence added
12/9	14/5	Strength of evidence added
13/2	14/8	Strength of evidence revised
13/3	14/9	Strength of evidence revised
13/5	14/11	Strength of evidence revised
13/7	15/1	Strength of evidence revised
13/8	15/2	Strength of evidence revised
14/5	16/1	Findings added for completeness
14/6	16/2	Edited for clarity
15/2	16/6	Fixed Typo, edited to match report body
15/7	16/11	Strength of evidence added
15/8	17/1	Edited for clarity and to match report body
16/5	17/10	Edited for consistency and clarity
16/10	18/5	Strength of evidence added to match report body
17/1	18/6	Strength of evidence added to match report body
17/2	18/7	Edited for clarity
17/3	18/8	Edited for clarity
17/5	19/1	Edited for consistency, fixed typos
17/8	19/4	Strength of evidence revised, strength of evidence added
18/2	19/6	Strength of evidence revised
18/3	19/7	Strength of evidence revised
18/5	20/1	Strength of evidence revised
18/7	20/3	Edited for clarity and consistency
19/2	20/8	Edited for clarity and consistency
19/5	21/1	Strength of evidence revised, edited for clarity
19/6	21/2	Strength of evidence edited to match report body, edited for clarity
19/9	21/5	Edited for clarity
20/3	21/9	Edited to match report body

20/4	21/10	Edited to match report body, strength of evidence revised
REPORT		
23/3	25/3	Edited for clarity
31/3	31/7	Edited for consistency
31/5	31/9	Edited for consistency
31/6	31/10	Edited for consistency
31/11	32/4	Edited for consistency
35/2	35/2	Edited for consistency
38/12	38/12	Revised to agree with Table 2
39/1	39/1	Reference edited for clarity
39/2	39/2	Reference edited for clarity, study findings added for completeness
40/5	40/5	Fixed typo
40/6	40/6	Paragraph deleted due to duplication
41/6	40/14	Strength of evidence added
41/9	41/2	Finding of non-significance added
41/12	41/5	Results edited for clarification
42/3	41/8	Edited for clarity
42/6	42/1	Edited for clarity, text deleted due to redundancy
43/2-6	42/3-4, 43/1	Revised for clarity
43/8-12	43/2	Revised for completeness
45/7-9	45/10-11	Revised for clarity
46/3	46/1	Fixed typo
47/7	47/8	Edited for clarity
47/8	47/9	Revised to agree with Table 4
47/9	47/10	Edited to agree with Table 4 and correct typos
47/10-11	48/1-2	Edited to agree with Table 4 and correct typos
48/3	48/6	Edited for completeness
48/4	48/7	Fixed typo
48/7	49/1	Number of included studies updated, added Lim (2011) findings to section
48/8	49/2	Fixed typo
49/1	49/3	Edited for consistency
49/5	49/4	Fixed typo
49/7-10	49/6-9	Edited for clarity
49/11	49/10	Edited for clarity, revised for completeness
49/12	49/11	Edited for clarity, revised for completeness
N/A	49/12	Findings added for completeness, new paragraph
N/A	50/4	Strength of evidence added for additional outcomes, new paragraph
50/7	50/7	Fixed typo

50/10	51/3	Fixed typo
51/1	51/5-6	Study quality rating added, findings added for completeness
N/A	51/6	Findings added for completeness, new paragraph
51/2	51/7	Strength of evidence revised
51/8	52/2	Findings added for completeness
N/A	52/3-4	Findings added for completeness, new paragraphs
N/A	53/7-9	Findings added for completeness, new paragraphs
52/10	54/1	Findings added for completeness
52/12	54/3	Findings moved to KQ1 and KQ2
N/A	54/4	Findings added for completeness, new paragraph
53/18	54/5	Strength of evidence added
53/18	55/1	Strength of evidence added, text deleted due to redundancy
55/16	56/17	Martino (2011) findings added to section
N/A	57/4	Strength of evidence added, new paragraph
56/5	58/2	Edited for clarity
57/1	58/3	Findings added for completeness
57/2-3	58/4-5	Edited for clarity
57/10	58/12	Fixed grammatical error
58/1-3	59/1-2	Findings added and revised for completeness
N/A	60/17-19	Strength of evidence and findings added for completeness, new paragraphs
N/A	61/1-2	Strength of evidence and findings added for completeness
59/9	61/4	Non-significance added
59/12	61/7	Edited for consistency
59/15	61/10	Strength of evidence revised, fixed typo, edited for clarity
61/3	63/1	Strength of evidence revised, edited for clarity
61/6	63/3	Edited for completeness, number of studies revised
61/7	63/4-9	Findings added for completeness
62/1	63/10	Revised for clarity
62/3	64/2	Study quality rating revised, edited for clarity
62/5-11	64/4-9	Edited for clarity and consistency
62/12	64/10	Edited for consistency
62/13	64/11	Edited for clarity
62/14	64/12	Edited for clarity
63/1	65/1	Strength of evidence revised, edited for clarity
63/3	65/3	Edited for clarity
63/4	65/4	Edited for consistency, strength of evidence added
64/5	66/3	Non-economic outcome removed , edited for clarity, strength of evidence revised
64/7	66/5	Fixed typo
65/9	67/7	Edited for clarity and consistency

66/2	67/13	Edited for clarity
66/7	68/5	Edited for clarity
67/1	68/7-14	Findings added/revised for completeness
67/2	68/15	Findings added for completeness and clarity
69/4	71/2	Strength of evidence revised, edited for clarity
70/9	72/4	Edited for clarity
71/1	72/5	Edited for clarity
71/2	72/6	Edited for clarity
73/1	74/2	Fixed grammatical error
73/8	74/9	Fixed typo
75/3	76/3	Edited for clarity
76/1	77/1	Edited for clarity
76/8	77/8	Edited for clarity
78/5	79/5	Findings added/revised for completeness
79/3	80/3	Strength of evidence added
80/4	81/3	Edited for clarity
83/5	84/3	Edited for clarity
85/5	85/7	Fixed typo
85/8	86/1	Edited for consistency
87/11	87/12	Edited for clarity
88/1	88/1	Edited for clarity
88/3	88/3	Edited for clarity
89/7	89/6	Text deleted
90/3	90/1	Edited for clarity
90/4	90/2	Findings added for completeness
90/6	90/4	Strength of evidence revised
90/7	90/5	Findings added for completeness
91/1	90/7	Strength of evidence added
91/11	91/8	Strength of evidence revised
92/3	92/1	Strength of evidence revised
93/5	91/10	Strength of evidence revised
93/10	93/4	Strength of evidence revised
98/5	97/4	Edited for clarity
99/3	98/1	Edited for clarity
101/5	100/3	Edited for clarity, fixed typo
103/5	102/2	Strength of evidence added, edited for clarity
104/2	102/5	Edited for clarity
106/5	104/11	Edited for clarity
108/6	106/6	Edited for consistency and clarity
110/4	108/2	Fixed typo
110-112/7	108-110/5	Hagen (2011) findings added to section, revised for clarity

115/7	113/7	Strength of evidence revised, strength of evidence added
116/12	114/5	Strength of evidence revised
117/2	115/1	Strength of evidence revised
118/1	115/7	Strength of evidence revised
119/6	117/1	Edited for clarity
122/10	119/12	Edited for clarity
123/4	120/6	Strength of evidence revised
124/1	121/2	Study quality added
124/2	121/3	Edited for clarity
125/3	122/3	Edited for clarity
126/7	123/5	Strength of evidence revised
127/3	124/1	Strength of evidence revised

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